Comments received via email in the CWHSP mailbox regarding the New B Reader Website

James Luckett, APRN-C
Lockheed Martin Missiles and Fire Control – Dallas
POB 650003, M/S: MED-00
Dallas, TX 75265-0003
Telephone: (972) 603-1806
Fax: (972) 603-2922
james.luckett@lmco.com

Just a comment on "Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings."

As a mid-level provider in occupational medicine for over 10 years and a background in interventional radiology, I would encourage the program for B Readers to be opened to the Mid-Level providers in occupational and environmental settings. This would include many fine clinicians that are PA's and Nurse Practitioners and would increase the utility of the program for pneumoconiosis identification by increasing the number of providers prepared to evaluate the radiographs and correlate them to physical exams.

Hervey Levin
6918 Blue Mesa Dr.
Dallas, Texas 75252-6140
972-733-3242-Office
972-733-3269-Fax
hervey@airmail.net
levinhp@umich.edu

Is there a federal register cite for these proposed "Recommendations"?
"Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings."

Steven E. Haber, M.D., F.C.C.P.
drshaber@txlung.com

In reviewing your proposed new site, I noted one area of concern.
Specifically, there are several areas that state or imply a diagnosis of pneumoconiosis CAN be made by x-ray alone.

For instance, in the section entitled "Applications for Chest Radiography in Occupational Health," subsection "Medical Diagnosis," you state: "Medical diagnosis of pneumoconiosis is NOT ALWAYS done by the radiograph alone" (emphasis added).

Later on, in discussing radiography as a component of clinical diagnosis, you state: "Workplace dusts can cause medical outcomes that OFTEN cannot be diagnosed based on the chest radiograph alone." This implies that sometimes it can.

The previous position of NIOSH, and in my opinion the correct one, was that there is nothing pathognomonic on an x-ray for pneumoconiosis, and therefore an x-ray alone can have abnormalities consistent with pneumoconiosis, but is never diagnostic of a pneumoconiosis.

Please consider rewording these areas. If left as is, this could lead to workers and others being diagnosed with a disease they might not have.

Patrick O'Connor
Kent & O'Connor, Incorp.
1990 M St., NW
Suite 340
Washington, DC 20036
202-223-6222
fax 202-785-0687

Attached are the comments of the American College of Occupational and Environmental Medicine on the document"Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings." **(see attached)**

If we can be of further assistance on this topic, please do not hesitate to contact me.

Wolfe, Anita L.

From: [redacted]
Sent: Wednesday, September 21, 2005 1:49 PM
To: Coal Workers' Health Surveillance Program, NIOSH
Subject: Comments on B-Reader Program and ILO Classification System
Attachments: ACOEM Comments re NIOSH.pdf

Attached are the comments of the American College of Occupational and Environmental Medicine on the document"Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings."

If we can be of further assistance on this topic, please do not hesitate to contact me.

Patrick O'Connor
Kent & O'Connor, Incorp.
1990 M St., NW
Suite 340
Washington, DC 20036
202-223-6222
fax 202-785-0687

AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

ACOEM Comments Regarding the NIOSH Web Page Concerning the B-Reader Program and ILO Classification System

The American College of Occupational and Environmental Medicine (ACOEM) includes more than 5,000 physicians and allied health professionals devoted to the study and practice of the specialty of occupational and environmental medicine. ACOEM's Occupational and Environmental Lung Disorders Committee has reviewed the recent NIOSH Recommendations for Applying the International Labour Office International Classification of Radiographs of Pneumoconiosis (ILO/ICRP) in:

1. Medical Diagnosis
2. Research and Population Surveillance
3. Worker Health Monitoring
4. Government Program Eligibility
5. Compensation Settings.

We believe that the above section of the NIOSH web page should be finalized, and offer the following comments:

We believe that the NIOSH web page on Chest Radiography and its subsections properly emphasize the utility of ILO/ICRP for purposes such as Research and Population Surveillance, and Worker Health Monitoring. Its role in Determining Government Program Eligibility is set forth in the applicable regulations, and is not at issue. With regard to Compensation Settings, the recent decision and other actions of Judge Janis Graham Jack underscore the risk of abuses which she termed "manufactured diagnoses,"[1] when chest radiographs were used in isolation by a small number of physicians who often diagnosed silicosis without ever seeing the thousands of patients allegedly so affected. We believe that such practices are to be deplored. Over-reading of chest radiographs by B readers has also been described,[2] although this study's design and conclusions have been criticized.[3]

As was conveyed to the NIOSH Public Meeting on the B Reader Certification Program in 2004 by ACOEM's then President Dr. John Holland,[4] ILO/ICRP should not be used for the diagnosis of particular individuals. For many physicians, the standard of care of the patient suspected of having a pneumoconiosis includes High Resolution Computed Tomography of the thorax as the preferred imaging technique.[5]

In agreement with the American Thoracic Society (ATS),[6] NIOSH emphasizes the need for physicians to base diagnoses of pneumoconioses on an information matrix, rather than solely on the basis of a B Reader's interpretation of plain chest radiographs. The matrix needs to include a detailed medical, occupational and environmental history, physical examination, pulmonary function measurements, and other laboratory testing.

Changes in technology in recent decades have made it inconvenient for many physicians to obtain high-quality thoracic radiographic images, in hard copy. While ACOEM realizes that regulatory constraints require continued use of conventional radiographic imaging and with ILO's standard comparison films, these constraints are not immutable. For example, the US Navy Asbestos Monitoring Surveillance Program (AMSP)[7] accepts digital films for workers exposed to asbestos in the past. The history, usefulness, and limitations of ILO/ICRP are well chronicled by Henry who calls attention to the fact that the transition to "filmless radiology"[8] began over a decade ago,[9] as well as by Attfield and Petsonk.[10] Investigators in other countries have published their initial, favorable findings from comparisons of

1990 M Street, N.W., Suite 340 Washington, District of Columbia 20036
202/785-5553 Fax: 202/466-7517 Web Site: www.acoem.org

ILO/ICRP readings by digital techniques vs. hard-copy plain radiographs in phantoms or patients.[11,12] Other enhancements such as computer-assisted classification may also be considered for inclusion in the process, aiming to reduce the variability in inter-reader and intra-reader interpretations.[13-15] ACOEM recommends that NIOSH devote further resources to enable a transition to digital radiography, including guidelines for soft-copy ILO classification of radiographs, as well as computer-assisted methods of analysis.

References

1. Anon. The Silicosis Sheriff. *Wall Street Journal.* (editorial). July 14, 2005.
2. Gitlin JN, Cook LL, Linton OW, Garrett-Mayer E. Comparison of "B" readers' interpretations of chest radiographs for asbestos related changes. *Acad Radiol.* 2004;11(8):843-56.
3. Gitlin JN, Cook LL, Linton OW, Garrett-Mayer E. Response to letters on B-readers study. *Acad Radiol.* 2004;11:1402-04.
4. Holland JB. B Reader Certification Program. Comments to NIOSH Public Meeting. Mclean, VA. March 4, 2004. www.acoem.org/gov/comments.
5. Gotway MB, Reddy GP, Webb WR, Elicker BM, Leung JWT. High-resolution CT of the lung: patterns of disease and differential diagnosis. *Radiol Clin N Am.* 2005;43(3):513-42.
6. American Thoracic Society. Diagnosis and Initial Management of Nonmalignant Diseases Related to Asbestos. *Am J Respir Crit Care Med.* 2004;170:691-715.
7. Navy Environmental Health Center. Asbestos Medical Surveillance Program Information Page. www-nehc.med.navy.mil/occmed/Asbestos.htm. Accessed 9/4/2005.
8. Henry DA. International Labor Office classification system in the age of imaging: relevant or redundant. *J Thorac Imaging.* 2002;17(3):179-88.
9. Mannino DM, Kennedy RD, Hodous TK. Pneumoconiosis: comparison of digitized and conventional radiographs. *Radiology.* 1993;187(3):791-6.
10. Attfield M, Petsonk L. Proficiency, procedures, and "B" readers classifications of radiographs for pneumoconiosis. *Acad Radiol.* 2004;11(12):1323-5.
11. Zahringer M, Piekarski C, Saupe M, et al. [Comparison of digital selenium radiography with an analog screen-film system in the diagnostic process of pneumoconiosis according to ILO classification]. *Rofo.* 2001;173(10):942-48. German.
12. Kroft LJ, Geleijns J, Mertens BJ, Veldkamp WJ, Zonderland HM, de Roos A.Digital slot-scan charge-coupled device radiography versus AMBER and Bucky screen-film radiography for detection of simulated nodules and interstitial disease in a chest phantom. *Radiology.* 2004;231(1):156-63.
13. Gurney JW. Pneumoconiosis assistant: a hypermedia-based classification of the pneumoconiosis. *J Thorac Imaging.* 1993;8(2):143-51.
14. Kraus T, Raithel HJ, Lehnert G. Computer-assisted classification system for chest X-ray and computed tomography findings in occupational lung disease. *Int Arch Occup Environ Health.* 1997;69(6):482-6.
15. van Ginneken B, Romeny BMH, Viergever MA. Computer-aided diagnosis in chest radiography: a survey. *IEEE Trans Med Imaging.* 2001;20(12):1228-41.

William S. Beckett MD MPH
Medical Director
Finger Lakes Occupational Health Services
University of Rochester School of Medicine
Rochester, NY
Bill_Beckett@URMC.Rochester.edu

I'm a medical director for one of the New York State Occupational Health Network clinics. At our last network meeting in Sept '05 we discussed your request for comments on the application of ILO classifications.

I have reviewed your draft materials, and it is the sense of the physicians and industrial hygienists of this statewide system, including 8 programs throughout the state, that we support the recommendations as presented by NIOSH. In addition, it was mentioned that we would support efforts to develop a standardized reading system for CT scans of the pneumoconiosis.

Please let me know if we can provide any further input.

Darrell K. Smith, CIH, MPH
Vice President, Government & Environmental Affairs
Industrial Minerals Association - North America
4061 Powder Mill Road, Suite 450
Calverton, MD 20705
301-595-5550
Fax 301-595-3303
darrellsmith@ima-na.org

The Industrial Minerals Association – North America is pleased to submit comments (attached as notes to the pdf) on the Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings. **(see attached)**

We apologize for submitting these after the October 15, 2005 deadline, but would appreciate your consideration and possible incorporation of these comments.

Please contact me if you have any questions.

Wolfe, Anita L.

From: Darrell Smith [darrellsmith@ima-na.org]
Sent: Tuesday, November 01, 2005 10:15 AM
To: Coal Workers' Health Surveillance Program, NIOSH
Cc: 'Mark G. Ellis (E-mail)'
Subject: Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Comp
Attachments: IMA Comments recommendationsNIOSH Proposal.pdf

To Whom It May Concern:

The Industrial Minerals Association – North America is pleased to submit comments (attached as notes to the pdf) on the Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings.

We apologize for submitting these after the October 15, 2005 deadline, but would appreciate your consideration and possible incorporation of these comments.

Please contact me if you have any questions.

Sincerely,

Darrell K. Smith, CIH, MPH
Vice President, Government & Environmental Affairs
Industrial Minerals Association - North America
4061 Powder Mill Road, Suite 450
Calverton, MD 20705
301-595-5550
Fax 301-595-3303
darrellsmith@ima-na.org
www.ima-na.org

NIOSH Topic Page

Chest Radiography

Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings

NOTICE: NIOSH Seeking Public Comment

The National Institute for Occupational Safety and Health is using the issuance of the new International Labour Office (ILO) Classification of Radiographs as an opportunity to expand its Web site on the B Reader Program and use of the ILO system. NIOSH-certified B readers use the internationally-recognized ILO system to classify chest radiographs for the presence and severity of pulmonary parenchymal and pleural changes potentially caused by exposure to dusts such as asbestos, silica, and coal mine dust. The revised program Web site provides more information about radiographic reading and the ILO system including recommendations or "best practices" for use of the ILO system in different settings.

Below is a draft of "Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings." We are seeking public comment for this document. Please review it and submit your comments to CWHSP@cdc.gov. If you would prefer to have a hard copy rather than electronic, please let us know, and we will be happy to fax or mail one to you.

Thank you in advance for your input. It is important to us that we consider many different viewpoints in this document. Also, we are interested in your feedback on the whole Web site. Please feel free to send any comments or suggestions to the same address.

Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final text will modified based on input received from stakeholders.

The International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses was developed primarily for use in epidemiological research. In this classification system, parenchymal lung abnormalities on chest radiographs are identified and radiographic severity is classified on a 12-point scale ranging from 0/- to 3/+ by comparing the radiographs to ILO standard films. Pleural abnormalities are also identified and described. Although the ILO system was developed primarily for use in research, the standardized descriptions of chest radiographs used in the system, and even the ~~scoring~~ classification system itself, have been applied in a wide range of settings. In some non-research settings, how or even whether ILO Classification should be applied has been controversial. In this document, guidance is provided for the roles of ILO Classification and NIOSH-certified B Readers performing ILO Classification in several important settings. Setting-specific suggestions for how ILO classifications should be performed are also provided.

A "Summary of Recommendations" is provided at the beginning of each section. Each addresses several critical issues. These concern the desirability of 1) using the ILO Classification for the specific purpose, 2) employing readers certified by the National Institute for Occupational Safety and Health (NIOSH) B Reader Program, 3) using single or multiple readings of chest radiographs, 4) employing "blind" reading to avoid potential biases from knowing employment and other details of the cases being classified, 5) using classification of quality control films to assess readers' tendencies to under- or over-classify films.

Summary of Comments on Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconios

Page: 1

Author: GlennR
Subject: Cross-Out
Date: 9/26/2005 10:49:15 AM -04'00'

Author: GlennR
Subject: Inserted Text
Date: 9/26/2005 10:49:30 AM -04'00'
classification

Radiography is only one component of medical testing for clinical diagnosis

No medical test, including chest radiography, is perfect. Chest radiography can miss some cases of dust-induced lung disease and falsely identify others. In addition, workplace dusts can cause medical outcomes that often cannot be diagnosed based on chest radiograph alone. For instance, inhalation of coal mine dust is associated not only with coal workers' pneumoconiosis but also with chronic obstructive lung diseases, such as chronic bronchitis and emphysema. In order to be accurate and comprehensive in their diagnoses, physicians must synthesize information from patients' occupational and medical histories (including dust exposures), symptoms, physical examinations, and medical testing. The type of medical testing depends on the suspected disease(s) and may include radiography, lung function testing, laboratory tests, and, in some cases, invasive testing such as lung biopsy. The American Thoracic Society (ATS) and other medical organizations publish official guidelines for diagnosis and management of respiratory diseases such as asbestosis. These guidelines emphasize the importance of using multiple diagnostic modalities. When available and appropriate, these guidelines should be used for the suspected disease [ATS 2004].

Single radiograph readings are appropriate

For medical diagnosis purposes, single radiograph readings are appropriate and do not need to be done as formal International Labour Office (ILO) classifications or by a certified B Reader. However, principles underlying the ILO Classification scheme for the pneumoconioses are applicable to clinical radiographic interpretation and can be useful in describing abnormalities, if present. Additional readings by a specialist or expert may be helpful in order to confirm a diagnosis in some situations. Although not needed for clinical diagnosis, ILO classification may eventually be required for participation in Federal or State compensation systems (see sections below on "Government Program Eligibility" and "Compensation Settings").

Timely disclosure of results, appropriate follow-up, and patient education are essential

Once the diagnosis is made, physicians should disclose results to the patient in a timely manner, provide appropriate medical follow-up, and educate patients about their illnesses and approaches to avoid or minimize further exposure to workplace dusts and other harmful exposures, e.g., tobacco smoke. Further exposure must be reduced to prevent progression of the disease, and appropriate treatment can minimize the impact of established disease.

Physicians must follow state reporting requirements

Physicians should be mindful that recognition of occupational lung disease can provide an opportunity for preventive interventions not only for the affected worker but also for the associated workplace, process, agent, or industry. Physicians and other health care providers are encouraged, and in some states required, to notify their State of diagnosed or suspected cases of occupational pneumoconioses, including silicosis and asbestosis. A chest radiograph classified or otherwise interpreted as consistent with the reportable disease is often considered sufficient evidence to require reporting. If physicians are not already aware of their State reporting requirements, they should contact their state to be apprised of any reporting requirements for which they may be responsible. Contacts for State Public Health Departments can be found on the Association for State and Territorial Health Officials (ASTHO) Web site (external link).

Physicians should also inform their patients about filing deadlines for state Workers' Compensation and Federal Black Lung benefits in order to preserve eligibility. The patient should be advised that there are often time limits that apply to how long individuals have to make a claim after they are diagnosed with a compensable disease.

References

Black Lung Clinics Program. Bureau of Primary Health Care, Health Resources and Services Administration
External Link: http://bphc.hrsa.gov/blacklung/default.htm

Page: 3

Author: GlennR
Subject: Note
Date: 9/26/2005 10:42:21 AM -04'00'
Line 17-18. The phrase, "do not need to be done as formal ILO classifications or by a certified B Reader" may be interpreted by the reader that a narrative clinical interpretation is sufficient. Since the entire guidance is for ILO classification, we presume the sentence refers to a Complete or Abbreviated Classification, but you might choose to make it clearer. The acronym ILO is already used and does not need to be spelled out.

Recommended Application of the ILO Classification System in Research and Population Surveillance

Draft proposal for public comment. The following should not be considered NIOSH policy but reflect preliminary efforts to disseminate guidance on best reading practices. The final text will modified based on input received from stakeholders.

Classifications undertaken for research and population surveillance of the pneumoconioses need to be accurate (valid) and precise (reliable). For example, reliably establishing temporal or geographic trends in disease prevalence or incidence, disease relationships with occupation and industry, and exposure-response relationships are all objectives that require consistent, reproducible ~~scoring~~ of films in order for the underlying effects to emerge. Thus, in these settings, accurately and precisely ~~scoring~~ films in relation to the International Labour Office (ILO) standard films is a critical goal and great care must be taken to attain it.

Summary of Recommendations

ILO Classification:	Yes
B Reader certification:	Yes
Multiple readings:	Yes
Blind reading:	Yes
Quality control films:	Desirable

Further information

The role of radiography in epidemiology and related research

The ILO International Classification of Radiographs of Pneumoconioses was designed as a mechanism for assessing occupational lung disease. It is based on classifying the degree of parenchymal lung abnormality on an unknown film on a 12-point scale ranging from 0/- to 3/+ by comparing it to ILO standard films [ILO 2000]. Pleural abnormalities are also identified and classified. Since its inception, ILO Classification has become a critical and necessary tool for investigation of the pneumoconioses. The validity of ILO Classification has been repeatedly demonstrated in many settings and industries. For example, classifications of radiographs of coal miners show clear correlations with dust exposure, lung dust burden, lung pathology, and mortality [Attfield 1992, Ruckley 1984, Miller 1985]. Elsewhere, classifications of radiographs of patients with asbestos-related lung disease were shown to be correlated with lung function [Cotes 1988]. A useful summary of criteria to consider for epidemiologic purposes is given by Mulloy et al. [1993].

Issues of reader variability

It is well known that variation exists not only from reader to reader (inter-reader variation), but also between readings by the same reader (intra-reader variation). Variation has been seen to persist despite careful training and extensive quality control [Fay 1959, Hurley 1982]. To reduce the effect of variation between readers in epidemiologic studies in order to derive the most precise data, it is recommended that at least two, but preferably more, readers each classify all radiographs independently [ILO 2000]. Use of panels reading films simultaneously is not recommended. Rather, readers should classify the radiographs alone and blind to the interpretations of other readers and to any information on the individual. These individual readings can be combined into a single summary classification. Summarization methods that represent the middle of the distribution of readings, such as use of median classifications, are preferable. Summarization methods that do not reflect the central tendency of the range of readings by their nature result in biased determinations and should be avoided.

Page: 5

Author: GlennR
Subject: Cross-Out
Date: 9/26/2005 10:50:14 AM -04'00'

Author: GlennR
Subject: Inserted Text
Date: 9/26/2005 10:50:25 AM -04'00'
classification

Author: GlennR
Subject: Cross-Out
Date: 9/26/2005 10:51:09 AM -04'00'

Author: GlennR
Subject: Inserted Text
Date: 9/26/2005 10:51:41 AM -04'00'
classifying

Select trained and experienced readers

Readers for epidemiologic studies should be selected to be representative of general reading practices: that is, they should not fall at the extremes of the range of variability between readers. The readers should be informed about and assessed for inter- and intra-reader variability.

A pilot trial and use of quality control film interpretation may be useful to assess the extent of inter-reader variation. Feedback should be provided to give passive encouragement to those in the extremes to moderate their readings. Alternatively, an active procedure of selecting readers based on their standing with respect to the others can be adopted.

Quality control

As noted above, initial and subsequent interval re-assessment of readers' performance in scoring quality control films is useful in documenting systematic differences between readers. Over time, variation between repeated classifications of the same films can also be used to assess whether "drift" in readers' scoring is occurring. Providing feedback to readers based on quality control evaluations is a useful strategy for narrowing the distribution and maintaining reproducibility of classifications relative to ILO standard films.

Quality control can be done simultaneously with interpretation of unknown films by placing unidentified quality control ("calibration") films with a previously established array of parenchymal and/or pleural findings within the set of unknown films being evaluated. An advantage to this approach is that it provides the most realistic assessment of how readers classify unknown films. Providing feedback comparing the reader's classification of these films to the previously-established classifications has been used to maintain and improve reader performance [Sheers 1978]. A National Institutes of Health-sponsored workshop suggested including chest films of unexposed workers in epidemiologic studies for purposes of control [Weill 1975].

Classify films blind to medical and exposure information

When classifying radiographs for epidemiologic purposes, it is essential to be aware that knowledge of supplementary details specific to individuals can introduce bias into results. This includes medical or exposure information and other readers' interpretations. [ILO 2000] To avoid the effects of any temporal reader drift, films collected over the course of a study can be allocated to readers in batches that are random with respect to time and other study characteristics.

References

International Labour Office (ILO). Guidelines for the Use of the ILO International Classification of Radiographs of Pneumoconioses, Revised Edition 2000 (Occupational Safety and Health Series, No. 22). International Labour Office: Geneva, 2002.

Attfield MD, Morring K. An investigation into the relationship between coal workers' pneumoconiosis and dust exposure in U.S. coal miners. *Am Ind Hyg Assoc J* 1992; 53:486-92.

Ruckley VA, Fernie JM, Chapman JS, et al. Comparison of radiographic appearance with associated pathology and lung dust content in a group of coalworkers. *Br J Ind Med* 1984; 41:459-67.

Miller BG, Jacobsen M. Dust exposure, pneumoconiosis, and mortality of coal miners. *Br J Ind Med* 1985; 42:723-33.

Cotes JE, King B. Relationship of lung function to radiographic reading (ILO) in patients with asbestos related lung disease. *Thorax* 1988; 43(10):777-83.

Page: 6

Author: GlennR
Subject: Inserted Text
Date: 9/26/2005 10:52:39 AM -04'00'
classifying

Author: GlennR
Subject: Inserted Text
Date: 9/26/2005 10:53:07 AM -04'00'
classifying

Workers diagnosed with pneumoconiosis should contact the State Office of Workers' Compensation to determine their eligibility

Federal benefits programs are completely separate from State Workers' Compensation programs. Some individuals may qualify for one program and not the other. State disability benefits and compensation differ by state, so contact the State Office of Worker's Compensation (external link) to learn about compensation from the State Government. There are often time limits that apply to how long individuals have to make a claim after the worker is diagnosed with a compensable disease, so workers should be encouraged to avoid delay in contacting the State Office.

Workers diagnosed with silicosis due to mining of tunnels at Department of Energy Facilities in Nevada or Alaska should contact the Energy Employees Occupational Illness Compensation Program to determine their eligibility

The Energy Employees Occupational Illness Compensation Program Act of 2000 provides compensation for employees or eligible survivors of employees of the Department of Energy, its predecessor agencies, and its contractors and subcontractors who became ill as a result of the work performed in the production and testing of nuclear weapons. Silicosis is a covered condition under the Act. Eligible employees are those who were exposed to silica for a total of at least 250 work days during the mining of tunnels at a Department of Energy facility located in Nevada or Alaska for tests or experiments related to an atomic weapon. Individuals with these exposures and seeking compensation should contact the Energy Employees Occupational Illness Compensation Program [EEOICPA Web site (external link)].

Employers should follow the OSHA asbestos standard

The Occupational Safety and Health Administration (OSHA) asbestos standard (external link) requires that chest radiographs obtained for surveillance of those exposed to asbestos be interpreted and classified by a B Reader, radiologist, or experienced physician with expertise in pneumoconioses. OSHA also specifies B Readers and the International Labour Office (ILO) Classification in its asbestos safety and health standards for general industry, construction, and shipyard employment.

References

Standards for Determining Coal Miners' Total Disability or Death Due to Pneumoconiosis. 20CFR718
External Link: http://www.dol.gov/dol/allcfr/Title_20/Part_718/toc.htm

Claims for Benefits Under Part C of Title IV of the Federal Mine Safety and Health Act, As Amended. 20CFR725
External Link: http://www.dol.gov/dol/allcfr/Title_20/Part_725/toc.htm

Black Lung Benefits Offices. Division of Coal Mine Workers' Compensation Program and District Offices, Department of Labor
External Link: http://www.dol.gov/esa/contacts/owcp/blcontac.htm

Energy Employees Occupational Illness Compensation Program Act of 2000, as described on the US Department of Labor compliance assistance web site.
External Link: http://www.dol.gov/esa/regs/compliance/owcp/ca_eeoic.htm

State Workers' Compensation Officials. US Department of Labor
External Link: http://www.dol.gov/esa/regs/compliance/owcp/wc.htm

Safety and Health Topics: Asbestos. Occupational Safety and Health Administration
External Link: http://www.osha.gov/SLTC/asbestos/index.html

Page: 12

Author: GlennR
Subject: Note
Date: 9/26/2005 10:41:33 AM -04'00'
Should a separate section be devoted to MSHA 30 CFR 50 reporting of Dust Diseases of the Lung. See link below to MSHA Program Policy Manual and pages 64 & 65 for pneumoconioses reporting. The policy contains specific criteria for ILO Classification and procedures for second interpretations.

http://www.msha.gov/REGS/COMPLIAN/PPM/PDFVersion/PPM%20Vol%20III.pdf

Single versus multiple readings

Despite concerns raised by the ILO, use of ILO Classification as performed by B Readers can be a useful tool in compensation proceedings. As the ILO states, "the object of classification is to codify the radiographic abnormalities of the pneumoconioses in a simple, reproducible manner" [ILO 2000]. Reproducibility is critical to using chest radiographic interpretations in compensation settings. Lack of accuracy and imprecise interpretation could lead to unequal treatment of claimants. To limit the impact of reader variability in scoring chest radiographs relative to ILO standard films, ILO recommends "that, in epidemiological studies, at least two, but preferably more, readers each classify all radiographs independently" [ILO 2000]. It may seem reasonable to consider applying the same standard in compensation proceedings after considering issues related to the effectiveness of the use of multiple readings (addressed below) and possible associated costs.

There are important caveats that should be considered in applying a multiple reading approach to compensation proceedings. As already discussed, there is inter- and intra-reader variability. Groups composed of individual readers with extreme tendencies of under- or over-reading of abnormalities can be expected to produce similarly extreme interpretations. Thus, use of multiple readings in itself will not guarantee accurate readings. There are several ways to deal with this issue and improve accuracy. One would be to select readers who are in the mainstream of reading tendencies and exclude those with extreme tendencies. This can be achieved in epidemiological studies by analyzing how groups of readers interpret the same films. In compensation proceedings, exclusion of readers may raise many issues and difficulties. Although desirable, selection based on quality control evaluation involving classification of test films does not necessarily guarantee how readers will classify actual unknown films. Similarly, interval quality control evaluation separate from actual readings, which is also desirable, does not guarantee that actual readings will be free of reader bias.

One potential solution to these issues might be to perform continuous quality control by mixing quality control ("calibration") films with those being read for compensation applications, with the identity of both sets of films hidden to prevent recognition of their source. Providing feedback comparing the readers' film classifications to previously-established classifications can be used as a tool to improve reader performance [Sheers 1978]. Furthermore, if sufficient numbers of quality control films are classified to achieve appropriate statistical power, evaluation of how readers classify these films can provide objective evidence of readers' performance and possible bias. However, the effectiveness of this approach in compensation proceedings has not been documented.

Another caveat to consider is how the classifications of multiple readers are combined into a single summary classification. Obtaining multiple readings and deriving summary classifications is a common strategy for improving precision. However, the approach to summarization can have an important effect on results. For instance, even if readers are providing accurate readings, methods that require consensus may reduce the proportion of radiographs read as positive to that, or below that, of the most stringent reader, thus compromising accuracy. On the other hand, use of median determinations will tend to reflect the center of the distribution of readers. Assuming the distribution is balanced, this may improve precision without negatively affecting accuracy. Although increasing the number of readers would theoretically increase the precision of readings, cost and complexity also increase with the number of readers. Depending on local circumstances, views may vary as to the specific number of readers that is optimal.

Classify films blind to medical, exposure, and contextual information

When classifying radiographs it is desirable that the reader does not consider any other information about the individuals being studied, including medical data, exposure information, the context and consequences of the reading, or other readers' interpretations. Awareness of supplementary details specific to individuals can introduce bias into results. This information should not be available to the reader at the time of chest radiograph classification but can be considered later when the chest radiograph classification is integrated with other clinical information to formulate a diagnostic assessment. Reading in a blinded fashion also has the potential to limit the appearance that conflict of interest is affecting results.

Page: 14

Author: GlennR
Subject: Inserted Text
Date: 9/26/2005 10:53:29 AM -04'00'
classifying

Catherine Inman, MD, MPH
Gundersen Lutheran
Occupational Health Services
1900 South Ave.
La Crosse, WI 54601-5494
(608) 775-6345

Got a call from a pulmonary doc yesterday who told me about the request for public comment. So I went to the B reader web site and found it very difficult to find the public comment part. I do have some suggestions--to advertise the request for public comment on the general b reader web page. I would not have known about it had it not been for my friend. Also, you might consider sending out this request to all of your B readers so at least they'd know about it. Anyway, these are just suggestions.

Lester Brickman
Professor of Law
Benjamin N. Cardozo School of Law
Yeshive University
brickman@yu.edu

Attached in two separate documents is Professor Lester Brickman's statement of qualifications and his commentary in response to NIOSH's call for public comment on the B Reader Program and use of the ILO system. **(see attached)**

To: National Institute for Occupational
Safety and Health (NIOSH)
CWHSP@cdc.gov

From: Lester Brickman

Date: December 22, 2005

Re: Comments on Proposed "B Reader Code of Ethics"

I am a professor of law at the Benjamin N. Cardozo School of Law of Yeshiva University and have written extensively on asbestos litigation, including a recent article titled *Ethical Issues In Asbestos Litigation*. In addition to my publications, I have testified before Congress on asbestos litigation on three occasions and been acknowledged as an expert on the history of asbestos litigation by two federal courts. I am submitting the following comments on NIOSH's proposed "Ethical Considerations for B Readers."[1]

It is appropriate, fitting and indeed essential that NIOSH address the ethical conduct of certain physicians involved in asbestos litigation who have been certified by NIOSH as B Readers.

Evidence has come to light in recent years to the effect that certain of these NIOSH-certified physicians are essentially selling their "diagnoses" for millions of dollars in fees -- indeed, that certain lawyers, doctors and screening enterprises have created a scheme to generate massive numbers of specious claims of nonmalignant asbestos-related injury. This presents a disturbing picture that NIOSH cannot continue to ignore.

NIOSH's proposal to establish a Code of Ethics for B Readers is a necessary but insufficient response to the evidence that "diagnoses" are being sold as if they were a commercial product. For the reasons set out in this comment, I am recommending to NIOSH that it establish a review procedure to audit B-reads prepared for litigation where there is evidence of clear abuse of the NIOSH certification. B Readers who fail the audit should have their certification removed.

Before setting forth my views on NIOSH's proposed Code of Ethics and my proposal for an audit procedure, I present a summary of the evidence to support my conclusion that X-ray readings are being sold, based largely on my own published writings[2] and the recent report by a federal judge presiding over a multi-district silica litigation.[3]

---

[1] A fuller statement of my qualifications to offer commentary on NIOSH's proposed "B Reader Code of Ethics," including a list of my publications, is attached as an appendix. I have been engaged by the Institute for Legal Reform, a nonprofit affiliate of the U.S. Chamber of Commerce, to review and comment on NIOSH's proposed "Ethical Considerations for B Readers." The comments I present are entirely my own and have not been reviewed by the U.S. Chamber or any other entity prior to this submission.

[2] A list of my published articles is set forth in the appendix to this comment. A leading legal affairs journalist, Stuart Taylor, has said of one of my articles, "Brickman's empirical research is so massive, his scholarship so meticulous and his 526 footnotes so crammed with compelling evidence, that his article should shift the burden of proof in public

The Rise of an Entrepreneurial Model

In my writings, I describe the radical shift in asbestos litigation that began in the mid to late 1980s, from the traditional model of an injured person seeking a lawyer to an entrepreneurial model that essentially reversed the process. The elements of the entrepreneurial model that I describe in my published writings include:

(1) a massive client recruitment effort undertaken by "screening" enterprises formed for that purpose which have been paid millions of dollars by lawyers to screen hundreds of thousands of former shipyard, construction and industrial workers in the past 15 years;

(2) generating virtually all of the nonmalignant claims of injury that have been brought -- historically these have made up 90 percent of asbestos claims -- though most of these "litigants" have no medically cognizable asbestos–related injury and cannot demonstrate any statistically significant increased likelihood of contracting an asbestos-related disease in the future;

(3) the claims of injury are often supported by entrepreneurially generated medical evidence, including: (a) evidence generated by the entrepreneurial screening enterprises and a comparative handful of B Readers and other doctors apparently selected because they produce X-ray readings and "diagnoses" which are not a product of good faith medical practice but rather a function of the millions of dollars a year in income that they receive for these services, and (b) pulmonary functions tests (PFTs) which are often administered in violation of standards established by the American Thoracic Society and which maladministration often results in findings of impairment which would not be found but for the improper administration of these tests;

(4) the claims of injury are further supported by "litigants'" testimony which frequently follows scripts prepared by their lawyers which are replete with misstatements with regard to: (a) identification and relative quantities of asbestos-containing products that they came in contact with at work sites (in order to shift the focus of testimony from certain manufacturers which have declared bankruptcy to others which are solvent), (b) the information printed on the containers in which the products were sold, and (c) their own physical impairments;

(5) being asserted mostly in a small number of jurisdictions which were selected, in part, because judges in those jurisdiction readily accommodated the interests of these "litigants" and their lawyers by dispensing with certain evidentiary requirements and proof of proximate cause, under a legal regime which I have termed "special asbestos law;"

---

debate to those who defend the legitimacy of the asbestos-claims industry," Stuart Taylor, Jr., *Asbestos Litigation: Evidence of Massive Corruption?*, NATIONAL JOURNAL, Jan. 3, 2004 at 8. Another leading journalist writing on asbestos litigation, Roger Parloff, commenting on the same article, stated that "[Brickman's] prodigiously researched article made his views more difficult to ignore and the evidence surfacing in . . . [the silica MDL] now takes him a grant step closer to vindication." Roger Parloff, *Diagnosing For Dollars*, FORTUNE, June 13, 2005 at 97, 98.

[3] *See In re Silica Prods. Liab. Litig.*, No. MDL 1553, 2005 WL 1593936, at *28 (S.D. Tex. June 30, 2005).

(6) being filed *en masse* in selected courts with the intention of overwhelming these courts' dockets and impelling the courts to aggregate the claims in order to move them through the judicial system;

(7) but which aggregations operate perversely to effectively preclude defendants from defending against most of the claims and to instead adopt settlement strategies that include payment of compensation irrespective of whether the litigants suffered any actual asbestos-related injury or whether any injury was substantially caused by exposure to that defendant's products, thus creating substantial incentives for plaintiffs' lawyers to increase recruitment efforts.

The core of the entrepreneurial model of nonmalignant asbestos litigation that I describe is the mass screening. Individuals who generally lack any health care knowledge or experience have set up approximately fifteen enterprises to "screen" hundreds of thousands of workers who could claim exposure to asbestos in their workplaces. Of the 850,000 asbestos claimants that have so far brought suit against over 8,400 different defendants,[4] perhaps as many as 600,000 have been recruited by these mass screenings. Many of the screening entities administer X-rays and several also administer PFTs for the sole purpose of generating evidence for litigation purposes. Mobile X-ray vans are brought to motels, strip malls and other locales to take X-rays at an assembly line rate of one every five to ten minutes and to administer the PFTs.

The Role of B Readers In Entrepreneurial Asbestos Litigation

To read these hundreds of thousands of pulmonary X-rays, screening enterprises and plaintiff lawyers hire NIOSH-certified B Readers. A comparative handful of B Readers, ranging from 4-6% of all certified B Readers,[5] are consistently chosen by plaintiff lawyers to read most of the hundreds of thousands of X-ray films generated by screenings. This small number of B Readers have accounted for a dramatically disproportionate number of the total number of X-ray readings that are submitted as medical evidence in support of nonmalignant asbestos personal injury claims.

The reliance on a comparative handful of B Readers and diagnosing doctors is a defining characteristic of the entrepreneurial model.[6] For example, The Manville Trust recently reported that as of August 30, 2005, it had received 691,910 claims, of which 499,766 included the name of the physician. The fifteen physicians whom the Trust has most frequently identified as the "primary

[4] *See* Lester Brickman, *Ethical Issues in Asbestos Litigation*, 33 HOFSTRA L. REV. 833, 834 (2005), accessible at ssrn.com/abstract=754188.

[5] As of December 15, 2005, NIOSH listed 387 B Readers on its website; on July 22, 2003, it listed 431; on April 25, 2002, it listed 535; and on February 20, 1998, NIOSH listed 627 B Readers.

[6] In the Silica MDL, Judge Jack noted that "the over 9,000 plaintiffs who submitted fact sheets were diagnosed with silicosis by only 12 doctors . . . affiliated with a handful of law firms and mobile X-ray screening companies." *In re Silica Prod. Litig., id.* at 30-31. A study of a stratified sample of claims submitted to Owens Corning before its bankruptcy filing indicated that just five B Readers (Drs. Raymond Harron, Jay Segarra, Richard Keubler, Philip H. Lucas and James W. Ballard) had read over 80% of the X-rays, with Dr. Harron alone accounting for 46% of the X-ray readings. Report of Dr. Gary K. Friedman at 11, 18, 21, Owens Corning Impaired Nonmalignant Claim Submissions 1994-1999 (approx.), (circa 2002). The Manville Trust reported that in a recent period, 49.6% of the tens of thousands of non-malignancy claims it received that identified a doctor were based on the B-reads of just 10 doctors.

physician" providing medical reports in support of claims, accounted for 200,107 or 40% of the 499,766 claims.[7] These fifteen physicians are listed below; those with asterisks (which I added) are now or have previously been certified as B Readers:[8]

Physicians		Claims as Primary Physicians
Ray A Harron	*	53,724
Alvin J. Schonfeld	*	28,645
Jay T. Segarra	*	23,325
Richard B. Levine	*	13,896
Dominc J. Gaziano	*	13,190
Larry M. Mitchell		11,606
James W. Ballard	*	11,111
Roy P. Johnson		9,610
Paul C. Venizelos	*	7,840
William H. Goldiner		5,461
Laxminarayana C. Rao	*	5,277
Robert J. Mezey	*	4,713
Robert A. Cohen	*	4,038
Joseph Buono		3,846
Robert B. Altmeyer	*	3,825
Subtotal – top 15		200,107
Trust Claims with Doctor Information		499,766
All Manville Trust Claims		691,910

The comparative handful of B Readers and diagnosing doctors, including those listed above, who are regularly selected by plaintiff lawyers, consistently grade most of the X-rays they read as 1/0 on the International Labor Office ("ILO") scale and "consistent with asbestosis" and mostly "diagnose" litigants as having mild asbestosis. For example, more than 90% of the 91,000 new claims presented to the Manville Trust in 2001 were 1/0 asbestosis claims mostly generated by attorney sponsored asbestos screenings and read by the same comparative handful of B Readers.[9]

---

[7] *See* Report prepared by David Austern, President, Claims Resolution Management Corp., for a Mealey's teleconference on November 30, 2005. The Manville Trust had previously reported that of 199,533 claims it processed in the period January 1, 2002 to June 30, 2004, just 20 B Readers accounted for 62% of the total B Readings. *See* Power Point Presentation at 8, David T. Austern, President, Claims Resolution Management Corporation, "2004 Asbestos Claim Filing Trends."

[8] The above table lists only the claims for which the listed doctors were deemed to be the "primary" physician. The table thus understates the actual concentration of physicians providing most of the medical reports in support of claimants. For example, though Dr. Ray A. Harron, a former B Reader, is listed as primary physician in 53,724 claims, he had actually provided medical reports in support of 76,274 individual Manville Trust claimants. *Id.*

[9] *See* THE FAIRNESS IN ASBESTOS INJURY RESOLUTION ACT OF 2003, S. Comm. on the Judiciary, 108th Cong., Report on S. 1125 (2003) (hereinafter the "FAIRNESS IN ASBESTOS INJURY RESOLUTION ACT OF 2003") (citing *Hearing on Asbestos Litigation, Before the Senate Comm. On the Judiciary*, 107th Cong. (2002) (statement of David Austern)); *id.* at 84 (citing Letter from Steven Kazan to the Honorable Jack B. Weinstein which states that "90% of the [Manville]

The Percent of "Positive" Readings By Entrepreneurial B Readers

B Readers and screening company representatives mostly testify that they do not know what percent of those that they screen they find positive for asbestosis (and therefore qualified to receive compensation). On the relatively few occasions when they do respond to questions about their "positive" rate, they assert that they find that 20-35% of the X-rays generated by their screenings are 1/0 (or higher) on the ILO scale.[10]

On the basis of my own research, I have concluded that the actual percentage of X-rays generated by attorney sponsored asbestos screenings which are read as 1/0 or higher by plaintiff lawyer selected B Readers is mostly in the 60-80% range.[11] For some B Readers and diagnosing doctors, the positive rates are even higher -- over 90 percent.[12]

The very high percentage of X-rays read by plaintiff lawyer-selected B Readers as 1/0 "consistent with asbestos," as well as the "diagnoses" of mild asbestosis made in reliance on those readings, is inconsistent with the findings of medical experts who have called asbestosis a "disappearing disease,"[13] and a condition that is "exceedingly rare."[14]

According to a number of medical studies which I reviewed, however, the actual incidence of lung conditions consistent with asbestosis in a population of workers with work-related exposure to asbestosis is 4% or less.[15] These medical studies and my own empirical research on the rates of "positive" B-reads and "diagnoses," lead to the conclusions that (1) the comparative handful of B Readers and other doctors regularly hired by plaintiff lawyers routinely and systematically over-diagnose the presence of lung conditions "consistent with asbestosis" and of nonmalignant asbestos-related disease to support entrepreneurially generated claims; and (2) that these B-readings and "diagnoses" are not the product of good faith medical practice but rather a function of the millions of dollars in fees available to be paid to B Readers and other doctors who consistently grade X-rays

---

Trust's last 200,000 claims have come from attorney-sponsored X-ray screening programs"). As reported in a recently published study, "[a] small number of B Readers has made reputations with attorneys by consistently interpreting chest radiographs of asbestos claimants as positive [i.e., 1/0 on the ILO scale] in 90-100% of cases." *See* Joseph N. Gitlin et al., *Comparison of "B" Readers' Interpretations of Chest Radiographs for Asbestos Related Changes*, 11 ACADEMIC RADIOLOGY 843, 844 (August 2004) (the "Gitlin Study").

[10] *See* Lester Brickman, *On The Theory Class's Theories of Asbestos Litigation The Disconnect Between Scholarship and Liability,* 31 PEPPERDINE LAW REV. 33 (2003-04), accessible at ssrn.com/abstract=490682.

[11] *See id.* at 86 for the empirical data on which this conclusion is based.

[12] For example, "after December 31, 2000 (when [the screening enterprise] N&M changed its focus from asbestos to silica litigation), Dr. [Ray] Harron [then a B Reader] found . . . [lung] opacities (consistent with silicosis) in 99.6% of the 6,350 B-reads he performed for MDL Plaintiffs. But prior to December 31, 2000 (when N&M focused on asbestos litigation), Dr. Harron performed B-reads on 1,807 of the same MDL plaintiffs for asbestos litigation and he found . . . opacities consistent with asbestosis but not silicosis. . . 99.11% of the time." *In re Silica Prods. Litig., id.* at 89-90 (fn. omitted).

[13] K. Browne, *Asbestos-Related Disorders*, OCCUPATIONAL LUNG DISORDERS 410 (3rd ed. 1994),

[14] Letter from Dr. James Crapo, FAIRNESS IN ASBESTOS INJURY RESOLUTION ACT OF 2003, Report at 18. Other medical researchers have stated that "we have not seen a single case of significant asbestosis with first exposure during the past 30 years." Jederlinic & Churg, *Ideopathic Pulmonary Fibrosis In Asbestos-Exposed Workers,* 144 Am. Rev. Resp. Dis. 695-96 (1991).

[15] I have summarized the medical evidence in *Theories of Asbestos Litigation, id.* at 46-54, 54-62.

as 1/0 on the ILO scale and "diagnose" mild asbestosis.[16] In recognition of this, the Manville Trust has recently announced that it is suspending acceptance of medical reports from certain doctors and screening enterprises:[17]

> The reliability of reports prepared by the doctors and screening facilities listed below has been challenged and is the subject of federal grand jury and congressional investigations into alleged fraud. Based upon evidence presented in the silica Multidistrict Litigation (MDL), the challenge is credible and compels suspension of acceptance of these reports. . . . Pending completion of the grand jury and congressional investigations and the litigation in which the reports were challenged, CRMC will no longer accept reports prepared by these doctors and facilities.
>
> In addition, CRMC has determined that medical reports prepared by Healthscreen, Inc., a pulmonary function testing (PFT) facility formerly located in Jackson, Mississippi (now closed), are not reliable and will no longer be accepted.
>
> Effective immediately, CRMC will not accept reports from the following doctors and screening facilities. . . .
>
> Dr. James Ballard* N&M, Inc.
> Dr. Kevin Cooper* RTS, Inc. (Mobile, Alabama)
> Dr. Todd Coulter Healthscreen, Inc. (Jackson Mississippi)
> Dr. Andrew Harron*
> Dr. Ray Harron*
> Dr. Glynn Hilbun
> Dr. Barry Levy
> Dr. George Martindale
> Dr. W. Allen Oaks*

Issues of Inter-Reader And Intra-Reader Variability

As stated by NIOSH, "[i]t is well known that variation exists not only from [B] Reader to [B] Reader, but also between readings by the same Reader (intra-reader variation)." The evidence I reviewed, however, indicates that both intra- and inter-reader variability is being used by the comparative handful of B Readers regularly selected by plaintiffs' lawyers to mask their participation in a scheme that U.S. District Court Judge Janis Jack concluded had been devised by lawyers, screening companies and doctors to "manufacture . . . [diagnoses] for money"[18] -- that is, to perpetuate fraud.

It is, of course, true that in any given case or even a set of hundreds of cases involving the X-ray detection of pleural plaques or very mild asbestosis, medical experts can and do differ in their

---

[16] *See* Theories of Asbestos Litigation, *id.* at 90-97.

[17] Announcement By David Austern, President, Claims Resolution Management Corp., Sept. 12, 2005 (asterisks added to denote B Readers); *see also* Jonathan D. Glater, *Asbestos Fund Bars 9 Doctors,* N.Y. TIMES, Sept. 15, 2005, at C1.

[18] *In re Silica Prods. Lit, id* at 150.

interpretations of the X-rays. Here, however, we are dealing with thousands and tens of thousands of X-ray readings by a comparative handful of B Readers. Here we have huge and consistent discrepancies between the interpretations of neutral X-ray readers not concerned about a future flow of revenue and the B Readers who realize, in the aggregate, tens of millions of dollars in repeat business, for consistently grading the X-rays used for litigation purposes as "consistent with asbestosis" or with pleural plaques. The discrepancies involved are not simply different profusion readings but also include other variables in a single read such as shape and size of any profusions, lung zone and the presence of pleural plaques. Accordingly, the possibility that these consistent discrepancies can be explained as mere "inter- or intra-reader variability" recedes to near zero.[19]

The Gitlin/Linton Study

This conclusion is buttressed by the results of a study undertaken by Dr. Joseph Gitlin and Mr. Otha Linton, of the Johns Hopkins Medical Institutions.[20]

Dr. Gitlin and Mr. Linton selected a panel of six distinguished B Readers to re-read 492 X-rays that had been previously read for litigation purposes by several of the B Readers regularly selected by plaintiffs' lawyers as showing parenchymal abnormalities of 1/0 or higher in 96% of the X-rays. The panel selected by Gitlin/Linton were not informed that the X-rays had previously been read for litigation purposes. Moreover, the X-rays were masked as to patient and source information.

The panel classified the films as 1/0 or higher in 4.5% of the 2952 readings. Moreover, the degree of inter-reader variability was narrow: three readers found irregularities in 1.6-1.8% of the X-rays; two other readers found irregularities in 2.4-3.5% and two readers found irregularities in 10.7-12.8% of the X-rays.

Based on a statistical analysis, the Johns Hopkins study determined that there was a probability of less than 1 in 10,000 "that the differences noted between initial and consultant readers are due to chance alone."[21]

---

[19] When as occurs in asbestos and silicosis litigation, a B Reader reads an X-ray as "1/0, consistent with asbestosis" and with profusions in all six zones and with an *en face* pleural plaque and several years later reads the same X-ray as "1/0 consistent with silicosis" and does not mention asbestosis or the *en face* plaque, that is not a case of intra-reader variability. Rather it is the sale of a "positive" reading or diagnosis by a medical professional certified by NIOSH which "accurate or not, is money in the bank." *In re Silica Prods. Litig., id.* at *60-61.

[20] Joseph N. Giltin et al., *Comparison of "B" Readers' Interpretations of Chest Radiographs for Asbestos Related Changes*," ACADEMIC RADIOLOGY 843 (August 2004). Dr. Gitlin, who has a PhD, is a biostatistician on the faculty of the department of radiology of the Johns-Hopkin Medical Institutions and has been a participant in designing studies of B Readers. Mr. Linton was principal staff to the American College of Radiology Task Force on Pneumoconiosis for 25 years, and a consultant to NIOSH, as well as a member of the ILO task force on its chest X-ray classification system.

[21] *Id.* at 850.

The Silica MDL

My conclusions that (1) the development of an entrepreneurial model of asbestos litigation has generated massive numbers of specious claims and (2) that the comparative handful of doctors regularly hired by plaintiff lawyers are not engaged in good faith medical practice but rather have entered into business transactions in which they are paid millions of dollars in exchange for a product which they are licensed to sell, namely, medical evidence to be used to support litigation claims, have been significantly substantiated by the findings of U.S. District Court Judge Janis Jack, appointed to preside over 10,000 silica claims which were centralized into a multi-district litigation.[22] Judge Jack found evidence that, in her words, demonstrated the "unreliability of B-reads in asbestos litigation."[23] While Judge Jack's findings were based on claims of silicosis, she was examining the operation of the same screening enterprises and the same B Readers and diagnosing doctors who had engaged in the identical procedures with regard to the generation of claims of asbestosis and the production of medical "evidence" in support of those claims. Judge Jack found that the diagnoses "were manufactured for money" as part of "scheme" in which "the lawyers, doctors and screening companies were all willing participants."[24] This is the equivalent of a finding of fraud. Referring specifically to Dr. Ray Harron, who has done tens of thousands of B-reads for asbestos litigation, Judge Jack found that with regard to his silicosis diagnoses, "Dr. Harron [found] evidence of the disease he was *currently* being paid to find."[25]

The NIOSH Proposal

NIOSH's attempt to deal with this corrupt behavior is long overdue. The issue now is whether the proposal to adopt "Ethical Considerations for B Readers" and other published proposals is a sufficient step to curb the practices that I have described in this submission -- the same practices which Judge Jack identified in her 249 page indictment of the scheme devised by lawyers, screening companies and doctors to gin up bogus claims of both silica and asbestos-related disease -- claims which have generated billions of dollars in settlements. The plain answer is NO. Ironically, while NIOSH set up the certification program to improve the process of diagnosis of pneumoconiotic and other pulmonary diseases, that program has become an integral part of the "scheme [to] manufacture . . . [diagnoses] for money."[26]

Recommendation: A Decertification Procedure

In response to the considerable body of evidence now produced and briefly summarized in this comment, that approximately 15-25 B Readers have engaged in improper conduct -- conduct which should be and apparently is the subject of grand jury and congressional investigations -- it is incumbent on NIOSH to create an audit process to allow review of the work of high volume B Readers. The process should provide for decertifying B Readers found to have provided X-ray

[22] *See In re Silica Prods. Liab. Litig.*, No. MDL 1553, 2005 WL 1593936, at *28 (S.D. Tex. June 30, 2005).
[23] *In re Silica Prods. Lit., id.* at 136.
[24] *Id.* at 150.
[25] *Id.* at 157 (emphasis added).
[26] *Id.* at 150.

readings which under no reasonable application of the ILO standards, could be found to be accurate. The audit process I propose would have the following components:

(1) Appointment by NIOSH of a distinguished unbiased panel of B Readers -- preferably ones who have not read substantial numbers of X-rays for either plaintiffs or defendants in asbestos or silica litigation -- to be available to review chest X-rays read for litigation purposes.

(2) Creation of a mechanism that would apply only to "litigation B Readers," that is, high volume B Readers who read more than 500 X-rays annually for litigation purposes, and who have no physician/patient relationship with the litigants, as follows:

(3) Upon presentation of a credible complaint that a litigation B Reader's interpretations depart substantially from conformance with ILO standards --

(a) provision for an audit of a sample of that B Reader's findings to determine whether a prima facie case of nonconformance has been established; and

(b) in appropriate cases, a review of a larger sample of that litigation B Reader's reports in a given time period by the distinguished NIOSH panel.

(4) In the event the panel concludes that a litigation B Reader has departed substantially from ILO standards, the panel shall recommend to NIOSH that it withdraw that B Reader's certification.

(5) Upon such a recommendation, NIOSH will notify the appropriate state licensing authorities and medical certification boards of the recommendation and itself take appropriate action.

In light of the formidable evidence summarized earlier in this commentary, this proposal to add some teeth to NIOSH's "Ethical Considerations for B Readers" is the minimum that NIOSH should undertake to carry out its mission and to avoid being deemed an accomplice after the fact to "a scheme [to] manufacture . . . [diagnoses] for money."[27]

This proposal is not a silver bullet that will cure the malady of doctors being "willing participants [in a] scheme [to] manufacture . . . [diagnoses] for money."[28] Obviously, the abusive if not illegal behavior of doctors, lawyers and screening companies requires a far more concerted response from prosecutors, judges, state and federal legislatures and medical licensing authorities

[27] *In re Silica Prods. Litig., id.* at 150.
[28] *Id.*

and specialty boards. Nonetheless, one component of that cure surely is NIOSH action to add some teeth to its Code of Ethics for B Readers.

APPENDIX

To

Comments on Proposed "B Reader" Code of Ethics

Statement of Qualifications of Lester Brickman

1. I have published six articles on asbestos litigation: *The Asbestos Litigation Crisis: Is There A Need For An Administrative Alternative?*, 13 CARDOZO L. REV. 1819 (1992); *The Asbestos Claims Management Act of 1991: A Proposal To The United States Congress,* 13 CARDOZO L. REV. 1891 (1992); *Lawyers' Ethics And Fiduciary Obligation In The Brave New World Of Aggregative Litigation,* 26 WM. MARY ENVTL. L. & POL'Y REV. 243, 272-98 (2001); *On The Theory Class's Theories of Asbestos Litigation: The Disconnect Between Scholarship and Reality,* 31 PEPP. L. REV. 33 (2004); *Ethical Issues In Asbestos Litigation,* 33 HOFSTRA L. REV 31 (2005); and *An Analysis of the Financial Impact of S.852: The Fairness In Asbestos Injury Resolution Act of 2005*, 27 CARDOZO L. REV. 991 (2005). In these articles, I discuss: the nature of asbestos-related disease; the history of asbestos litigation, including the rise of an entrepreneurial model and screening enterprises; the use of mass screenings to generate mass filings of unimpaired claims; "diagnoses" of asbestosis by a comparative handful of B-readers and other doctors who are responding to substantial financial incentives rather than engaged in good faith medical practice; the use of witness preparation techniques with regard to product identification as a means of constantly renewing the supply of solvent defendants to replace and supplement those that have declared bankruptcy; the effects of forum selection on claim values; the impact of judicial responses to mass filings including mass consolidations and joinders on asbestos litigation; the resort to "inventory" and other settlement strategies in response to these aggregations; the role of contingency fees in the claiming process; ethical issues in asbestos litigation with a specific focus on asbestos bankruptcy proceedings; and an analysis of the costs that would be incurred for resolution of personal injury asbestos claims if S.852 (the "FAIR" Act) is enacted.

2. In 1991, I was requested by the Administrative Conference of the United States, an agency in the executive branch of the federal government, to draft a proposed administrative alternative to asbestos litigation and to organize a colloquy to consider and debate that proposal. As stated by the Chairman of the Administrative Conference:

> [W]e asked Professor Lester Brickman to prepare a paper proposing an administrative claims solution for comment and criticism by the panel, and we look forward to comments by the audience. Let me introduce Professor Brickman, who teaches law at Cardozo Law School, Yeshiva University. He is a leading authority in the area of attorney's fees and has written numerous articles on the subject. Professor Brickman became interested in the subject of asbestos litigation some years ago when he was hired as a consultant by one of the defendants in the asbestos litigation to review contingent fee issues. He has since had the opportunity to extensively review empirical data, case files,

and other materials on the subject. Because of his work in this area, we asked Professor Brickman to draft a proposed administrative solution which our panelists have been invited to criticize.

Administrative Conference of the United States, Colloquy: *An Administrative Alternative To Tort Litigation To Resolve Asbestos Claims,* October 31, 1991, Transcript at 4.

To participate in the colloquy, I invited: U.S. District Court Judge Jack Weinstein; Deborah Hensler, a senior social scientist at the Rand Civil Justice Institute; Ronald Motley, a leading plaintiffs' attorney; Andrew Berry, a leading defendants' attorney; Howard D. Samuel, President, Industrial Union Department of the AFL-CIO; and Judge G. Mervin Bober, Associate Chief Administrative Law Judge, U.S. Department of Labor.

3. On the basis of the expertise I had developed and the work I did for the Administrative Conference, as well as additional research I undertook which included accessing then unpublished data compiled by the Manville Trust and the Rand Foundation, I published two law review articles in 1992, which are the first two articles listed in ¶1. The first one listed is an analysis of asbestos litigation and has been cited by the U.S. Supreme Court, federal courts of appeals, state courts, casebooks and scores of scholarly articles as indicated in my Curriculum Vitae ("CV") which I attach to this Appendix.

4. In the other article generated by the colloquy, I set forth the proposed legislation which I drafted. Under that proposal, all claims of injury due to exposure to asbestos-containing products would be removed from the tort system and channeled to an industry-financed trust fund to pay claims to those injured and impaired by exposure to such products. The proposal included the establishment of an Asbestos Claims Management Board within the Office of Workers Compensation of the U.S. Department of Labor to promulgate medical criteria for eligibility and to create and administer a claims procedure in accordance with the provisions of the proposed act. In preparing the proposal, I consulted other proposals for setting up an administrative process as an alternative to the tort system. In addition, in the article, I analyzed constitutional and policy questions raised by interposing an administrative agency for payment of claims in place of the tort system.

5. In October 1991, I was also invited to testify before a subcommittee of the Judiciary Committee of the House of Representatives which was holding hearings on the asbestos litigation crisis. My prepared remarks were titled: *Effects Of Asbestos Injury Litigation On Federal And State Courts.* I was not retained for that purpose and received no compensation for my testimony.

6. In a 2001 law review article on aggregative litigation, the third article listed in ¶1 of this Appendix, I devoted approximately 30 pages to a discussion of asbestos litigation. For

this article, I conducted extensive research on asbestos claiming behavior and the resulting impact on asbestos trusts. I examined how typical "exposure only" asbestos cases are developed and processed; the origin of the Manville Trust, the first bankruptcy trust, which was created in the aftermath of the bankruptcy of the JohnsManville Corporation; the trust distribution procedures ("TDP") which it adopted and which became a model for subsequent asbestos trusts; the Trust's later attempt to develop and apply an audit program to identify and weed out claims which lacked minimally requisite medical documentation and which reflected extraordinarily high incidences of misdiagnoses by a handful of B-readers; and conflicts of interest created by plaintiff lawyers' contingency fee arrangements. I also examined the recent trend towards aggregating litigations, including asbestos litigation; the enormous financial incentives unleashed by such aggregations; and the effect of those financial incentives on litigation behavior, in particular, the coercive effect on defendants and the perverse effects on the generation of claims because of the incentives for lawyers to recruit new claimants to replenish their "inventories" of claims.

7. In April, 2003, I was invited to be one of fifteen panelists to speak at a symposium on *ASBESTOS LITIGATION & TORT LAW: TRENDS, ETHICS, AND SOLUTIONS,* at the Pepperdine Law School. Among the panelists and speakers were the Hon. Alfred Chiantelli, formerly Coordinator of Asbestos Litigation for the San Francisco Superior Court; Professor Roger Cramton of the Cornell Law School; Professor Deborah Hensler of the Stanford Law School, co-author of the RAND Corporation reports on asbestos litigation; Professor Frances McGovern of the Duke University School of Law, Professor George Priest of the Yale Law School, Victor Schwartz, of Shook, Hardy, & Bacon; the Hon. Griffin B. Bell of King & Spalding, and formerly Attorney General of the United States; Steven Kazan of Kazan, McClain, Edises, Abrams, Fernandez, Lyons & Farrise; and Alan Brayton of Brayton Purcell.

8. In the article that I prepared for the symposium, which was published in January 2004, I analyze asbestos litigation including an extensive empirical description and analysis of attorney-sponsored asbestos screenings and the role that such client recruitment efforts play in the litigation. To do so, I consulted the deposition testimony of approximately forty screening company principals, their key employees and the B-readers and other doctors they retained, as well as numerous other litigation documents. I address, *inter alia,* the fact that attorney sponsored asbestos screenings have no medical purpose and are undertaken for the sole purpose of generating an inventory of clients for the lawyers underwriting the screening. I further address the financial incentives that pervade this mass recruitment process and how those incentives influence and are reflected in: (1) the actions of B-readers and other doctors involved in rendering diagnoses and producing medical evidence in support of the claimants so recruited; and (2) the administration of pulmonary function tests by the screening enterprises to generate further support for the claims that were generating. On the basis of the documentary evidence I consulted, I was able to reach the conclusion that asbestos screening companies routinely failed to adhere to American Thoracic Society standards in administering pulmonary function tests; I also discuss the consequences of their failure to do so. (I have since obtained copies of analyses by leading medical experts of the accuracy of pulmonary function tests administered by screening enterprises which fully corroborate the conclusions I reached). I also consider the

efforts of the Manville Trust to amend its Trust Distribution Procedures to implement an audit procedure in response to tens of thousands of asbestos injury claims presented with inadequate medical documentation or with spurious documentation provided by a select few B-readers, whose diagnoses and reports, according to most neutral medical experts and scientists, lack credibility. I also consider how other asbestos trusts have been plagued with similar volumes of abusive claims and why attempts to resolve the inadequacies of the bankruptcy trust distribution procedures have foundered.

9. In June 2003, I was requested by the staff of the U.S. Senate Committee on the Judiciary to allow them to review parts of the draft article in connection with hearings that were being planned on legislation addressing the asbestos litigation crisis. Senator Jon Kyl of Arizona cited the forthcoming article, with approval, in the Report of the U.S. Senate Committee on the Judiciary on S.1125.

10. In recent years, I have been invited to appear as a panelist or presenter at numerous conferences and programs on asbestos litigation. I have declined most of these invitations because of my teaching schedule and other responsibilities. In 2004, I accepted two invitations. In June, I was a presenting panelist at the HarrisMartin "Conference on Asbestos Allocation: Apportionment Liability In Asbestos Litigation." My topic was "Ethical Issues in Asbestos Litigation. (The article on ethical issues in asbestos litigation that I list in ¶1 is an outgrowth of that presentation). I also was a presenting panelist at the Mealey's National Asbestos Conference in September 2004, and spoke on the failure of asbestos screenings to adhere to a medical model for screening of an exposed population.

11. In 2003, I was retained as a consultant by counsel for an insurance company to prepare an expert report which was filed in the Western Asbestos Company bankruptcy. *In re Western Asbestos Co., et al., Debtors*, Bankr. N.D. Calif., No. 02-46284 (LT). In that report, I presented an overview of asbestos litigation, the resort to inventory settlements, an analysis of bankruptcy trusts including extensive discussion of the Manville Trust, the lessons to be drawn from the experiences of the Manville Trust and other asbestos bankruptcy trusts and an analysis of the proposed plan of reorganization with a focus on the trust distribution procedures being proposed. My qualifications as an expert on these matters were challenged by plan proponents in the form of a "*Daubert*" motion. The bankruptcy court rejected the challenge. *In re Western Asbestos Co., et. al.*, Debtors, 2003 Bankr.LEXIS 1894 at *3 (Oct. 31, 2003).

12. In 2004, I was retained by counsel for a group of banks to prepare an expert report which was filed in the Owens County bankruptcy. In re *Owens Corning et al., Debotrs,* Bankr. D. Del. No. 003837. In that report, I presented an overview of asbestos litigation, the rise of what I termed an entrepreneurial model of asbestos claiming, the components of which include: mass screenings by enterprises hired by attorneys; the use of a comparative handful of B-readers who consistently find very high rates of asbestosis even though neutral medical experts find that only a very small fraction of the X-rays are consistent with asbestosis; the routine

maladministration of pulmonary function tests by screening enterprises in order to generate false evidence of impairment; the use of witness preparation techniques to implant false memories; mass filings of claims generated by the screenings; the judicial resort to aggregations in response to the mass filings; leading to the rational but futile resort to "inventory" settlements of claims even though there was often no evidence of actual illness or significant product exposure. I also questioned the accuracy of projections of future numbers of asbestos claimants based upon historical settlement patterns and discussed recent changes in the tort system which have resulted in dramatic decreases in the number of nonmalignant asbestos claims.

13. Once again, my qualifications to testify as an expert on the matters related above were challenged by Plan Proponents in the form of a "*Daubert*" motion and once again, the court rejected the challenge. *Owens Corning et al., v. Credit Suisse First Boston, et al.*, Order, Jan. 10, 2005, Bankr. D. Del. No. 0400-905.

14. I also testified in the Owens Corning proceeding before Judge John P. Fullam. Judge Fullam's decision acknowledged a number of the issues that I raised in my expert report and in my testimony. *Owens Corning et al., v. Credit Suisse First Boston*, et al., Memorandum And Order, at "Litigation History," March 31, 2005, Bankr D. Del. No. 04-00905.

15. In July 2004, I testified before the Subcommittee on Commercial And Administrative Law of the U. S. House of Representatives Committee on the Judiciary. I focused my remarks on the process of administering the bankruptcies of former producers and sellers of asbestos containing products. More specifically, I provided the subcommittee with an overview of asbestos litigation and a summary of my research findings. In addition, I addressed the formation and administration of asbestos bankruptcy trusts, the effect of the adoption of §524(g) of the Bankruptcy Code on the development of plans of reorganization, the abuses prevalent in prepacked bankruptcies, and an analysis of conflicts of interest that had become endemic in asbestos bankruptcy proceedings.

16. On February 2, 2005 I testified before the U.S. Senate Judiciary Committee which was holding hearings on the Fairness in Asbestos Injury Resolution (FAIR) Act of 2005. In my testimony, I related how some plaintiff lawyers had recycled thousands of previous claims of asbestosis as silicosis claims even though the four doctors who testified at the hearing stated that they had virtually never encountered someone who had both asbestosis and silicosis. My testimony was the subject of an article in the New York Times which appeared on the morning of the hearing. *See* Jonathan D. Glater, *Companies get Weapon in Injury Suits*, NEW YORK TIMES, February 2, 2005 at Cl. My testimony also formed the basis for an extensive analysis of the silicosis "epidemic" which appeared in Fortune Magazine in July 2005. Roger Parloff, *Diagnosis For Dollars*, FORTUNE, June 13, 2005 at 97. Both Mr. Parloff and Mr. Glater observed that the real significance of the information generated through the extensive discovery permitted by Judge Jack extended well beyond the conclusion that most of the approximately 10,000 silicosis claims were simply unsupportable and likely fraudulent. Rather, the significance

was that it cast substantial doubt on the validity of tens of thousands of claims of asbestosis which generated hundreds of millions of dollars in settlement payments — claims which were recruited by the same screening enterprises and supported by medical evidence generated by the same doctors that Judge Jack excoriated.

17. In January, 2005 I was invited by the President of the United States, George W. Bush, to join him on stage at an event in McComb County, Michigan, to explain to a "town hall" audience the abuses that had developed in asbestosis litigation. A transcript of that event is available at www.whitehouse.gov/news/releases/2005/01/20050107-8.html#.

Allan R. Goldstein MD
arg50a@aol.com

I have reviewed the draft of "Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis , Research and Population Surveillance , Worker Health Monitoring , Government Program Eligibility , and Compensation Settings ." My comments are based on being a board certified pulmonologist , a B-reader and an expert witness in suspected cases of occupational pneumoconiosis and/or asthma . First of all , I would like to congratulate the authors of these recommendations for tackling this monumental task . On page 2 lines 22-32 please give consideration to providing some means of automatically providing a list of pulmonary physicians who are willing to and capable of providing appropriate evaluation and care of those with occupational exposures known to be related to the development of pneumoconiosis . I also have concerns on page 3 , lines 4-6 . This implies that exposure to coal mine dust , in and of itself , causes CWP . Though the literature does support chronic cough in simple CWP , I do not believe that the literature supports emphysema except in cases of PMF . I would hope that final draft of these Recommendations does not allow attorneys on either side to base their arguments on "NIOSH policy" . Thank you for the opportunity to submit my thoughts on this very important issue.

Laura S. Welch, MD
CPWR
8484 Georgia Ave, Suite 1000
Silver Spring, MD 20910
301-578-8500

The B reader page has a new section on ethics. Although you are not soliciting comments on that section specifically, I want to send a comment in case that section is still under review.

I think this section is very good except for the last provision, that a B reader notify NIOSH if he/she has a license suspended or is under review for such. As far as I can tell from the B reader page, there is no requirement in the documentation for the B reader program that NIOSH requires a B reader to be licensed to practice medicine. Is it not permissible for a B reader to retire from medical practice and still be a B reader?

If the requirement to have an active medical license does exist, there would need to be a written document stating what NIOSH would do if a B reader reported suspension or review of a license, or if a reader did not report a suspension. Hospitals and insurance companies require this information, and have active peer review organizations to address questions that come up. Suspension of a license does not always lead to loss of hospital privileges, for example.

This reporting requirement will add additional work for the B reader program, and I don't think it adds additional value to the statement of ethics. I would recommend that requirement be deleted.

If this page is final, then I would recommend NIOSH develop a written plan on what will happen to a physician who puts a license on inactive status or whose license is suspended.

Mark A. Behrens, Esq.
Shook, Hardy & Bacon L.L.P.
Hamilton Square
600 14th Street, N.W., Suite 800
Washington, D.C. 20005-2004
ph. (202) 639-5621
fax (202) 783-4211

Attached please find comments submitted on behalf of the Coalition for Litigation Justice, Inc., American Insurance Association, National Association of Manufacturers, National Federation of Independent Business Legal Foundation, National Association of Wholesaler-Distributors, Property Casualty Insurers Association of America, National Association of Mutual Insurance Companies, American Tort Reform Association, and International Safety Equipment Association with regard to the following proposed documents: (1) "Ethical Considerations for B Readers" and (2) "Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographers of Pneumoconioses In Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings." **(see attached)**

Behrens, Mark (SHB)

[redacted]

Sent: Friday, January 13, 2006 4:28 PM

To: 'CWHSP@cdc.gov'

Subject: Coalition et al. NIOSH Submission 1/13/06 (2 attachements)

Attached please find comments submitted on behalf of the Coalition for Litigation Justice, Inc., American Insurance Association, National Association of Manufacturers, National Federation of Independent Business Legal Foundation, National Association of Wholesaler-Distributors, Property Casualty Insurers Association of America, National Association of Mutual Insurance Companies, American Tort Reform Association, and International Safety Equipment Association with regard to the following proposed documents: (1) "Ethical Considerations for B Readers" and (2) "Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographers of Pneumoconioses In Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings."

Mark A. Behrens, Esq.
Shook, Hardy & Bacon L.L.P.
Hamilton Square
600 14th Street, N.W., Suite 800
Washington, D.C. 20005-2004
ph. (202) 639-5621
fax (202) 783-4211

COALITION FOR LITIGATION JUSTICE, INC., AMERICAN INSURANCE ASSOCIATION, NATIONAL ASSOCIATION OF MANUFACTURERS, NATIONAL FEDERATION OF INDEPENDENT BUSINESS LEGAL FOUNDATION, NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS, PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA, NATIONAL ASSOCIATION OF MUTUAL INSURANCE COMPANIES, AMERICAN TORT REFORM ASSOCIATION, AND INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION'S COMMENTS ON NIOSH'S PROPOSED "ETHICAL CONSIDERATIONS FOR B READERS"

The Coalition for Litigation Justice, Inc., American Insurance Association, National Association of Manufacturers, National Federation of Independent Business Legal Foundation, National Association of Wholesaler-Distributors, Property Casualty Insurers Association of America, National Association of Mutual Insurance Companies, American Tort Reform Association, and International Safety Equipment Association are pleased to offer the following comments on the National Institute for Occupational Safety and Health (NIOSH)'s proposed "Ethical Considerations for B Readers." As discussed below, we believe that while a B Reader Code of Ethics is an important step, much more needs to be done if NIOSH is going to address the significant problems posed by the participation of NIOSH-certified B Readers, in mass litigation screenings used to generate tens of thousands of unwarranted asbestos and silica lawsuits.

I. History of the NIOSH B Reader Program

The NIOSH B Reader Program came about when the Black Lung Benefit Act of 1972[1] created a demand for physicians that could interpret conventional chest x-rays for changes consistent with coalworkers' pneumoconiosis.[2] A 1973 study of chest x-ray interpretations from a medical surveillance program for coalworkers' administered by NIOSH found that the level of interreader variability was unacceptable even when using the International Labor Office (ILO) System for Classification of Radiographs for the Pneumoconioses.[3] The B Reader Program was established to reduce the level of variability among readers interpreting chest x-rays by objectively documenting proficiency in evaluating the characteristics and patterns of images on the chest x-ray for occupationally related lung disease.[4]

Since its inception, the NIOSH B Reader Program has attained high visibility in the United States and throughout the world. It continues to have important uses in dust-disease research, in surveillance of dust-exposed workers, in the clinical practice of medicine, and in certain workplace regulations. Unfortunately, however, and through no fault of NIOSH, its use in disease compensation programs, and

---

1 Black Lung Benefits Act of 1972, Pub. L. No. 92-303, 86 Stat. 150 (1972) (codified at 30 U.S.C. §§ 901 *et seq.*).

2 *See* Robert Glenn, *The NIOSH B Reader Program: Recalling Its True Purpose*, 16 PRODS. LIAB. 1, 3 (ABA, Sec. of Litig., Comm. on Prods. Liab. Litig.) (Winter 2005).

3 *See* Benjamin Felson, et al., *Observations on the Results of Multiple Readings of Chest Films in Coal Miners' Pneumoconiosis*, 109 RADIOLOGY 19, 23 (1973).

4 Glenn, *supra*, at 3.

most notably in litigation involving asbestos and silica, has resulted in widespread abuses that only appear to be increasing over time.[5]

II. A Serious Problem Has Emerged

As NIOSH notes in its November 17, 2005 Federal Register announcement, [6] a recent decision by Judge Janis Graham Jack of the United States District Court for the Southern District of Texas raised serious questions regarding the ethical conduct of certain physicians, including NIOSH certified B Readers, in diagnosing cases of silicosis. Of seven physicians singled out by the Judge in her ruling on the reliability of those diagnoses -- under the guidelines set forth by the United States Supreme Court in *Daubert v. Merrell Dow. Pharm., Inc.*, 509 U.S. 579 (1993) -- five were certified NIOSH B Readers.

The problem, as Judge Jack noted in her opinion, is that positive B Reads, come with the stamp of approval of a NIOSH-certified physician and are often considered proof positive of a diagnosis[7] even though it is universally accepted in the medical profession that a chest x-ray alone is not diagnostic of a pneumoconiosis.[8] The silicosis diagnoses upon which the silica suits had been filed rested primarily upon a positive ILO classification. As Judge Jack noted,

---

5 *Id. See also* Nathan Schachtman, *Silica Litigation: Screening, Scheming & Suing*, Washington Legal Foundation, Critical Legal Issues, Working Paper Series No. 135 (November 2005).

6 *See Federal Register,* Vol. 70, No. 221, Thurs., Nov. 17, 2005, 69765, 69766.

7 *See In re Silica Prods. Liab. Litig.*, No. MDL 1553, 2005 WL 1593936 at * 51 (S.D. Tex. June 30, 2005).

8 *See, e.g.* Robert M. Ross, *The Clinical Diagnosis of Asbestosis in This Century Requires More Than a Radiograph,* 124 CHEST 1120-28, 2003.

> some of the Plaintiffs' lawyers and even the doctors seemed to enter the Daubert hearings under the impression that a positive B-read is a talisman that would dispel any doubts about the diagnoses as a whole.[9]

But while these doctors were able to pass the difficult B Reader examination, by consistently and accurately interpreting chest films according to the ILO system, when they applied this classification system in the silica litigation context, they misread the films to advance the litigation interests of the claimants.[10] Indeed, one of the most remarkable statistics presented to Judge Jack was that over 6,000 of the 10,000 silicosis plaintiffs before her had also filed asbestos-related claims.[11] According to the medical experts who testified, the number of silica claimants who also had made an asbestos-related claim was "stunning and not scientifically plausible."[12] Judge Jack ultimately concluded that "a golfer is more likely to hit a hole-in-one than an occupational medicine specialist is to find a single case of both silicosis and asbestosis."[13]

---

9 *See In re Silica Prods. Liab. Litig.*, 2005 WL 1593936, at *51.

10 *See* Schachtman, *supra*, at 6. *See also In re Silica Prods. Liab. Litig.*, 2005 WL 1593936, at *53-54.

11 *In re Silica Prods. Liab. Litig.*, 2005 WL 1593936, at *31, 53. *See also* David Hechler, *Silica Plaintiffs Suffer Setbacks: Broad Effects Seen in Fraud Allegations*, NAT'L L. J., Feb. 28, 2005, at 18.

12 *See In re Silica Prods. Liab. Litig.*, 2005 WL 1593936, at *53 (quoting Dr. John Parker, former administrator of NIOSH's B reader program); *see also id.* ("[I]n the cases that I've had pathology to evaluate, I have never seen cases in which there was both silicosis and asbestosis in the same patient.") (quoting Dr. Hammar); *id.* ("Even in China, where I saw workers with jobs involving high exposure to asbestos and silica . . . , I did not see anyone or review chest radiographs of anyone who had both silicosis and asbestosis.") (quoting Dr. David Weill, Senate Judiciary Committee Testimony, Fed. Doc. Clearinghouse at 4 (Feb. 3, 2005)); *id.* ("Among the thousands of chest x-rays which I reviewed in asbestos and silica exposed individuals, I cannot remember a single chest x-ray which showed clear-cut findings of both asbestos exposure and silica exposure.") (quoting Dr. Theodore Rodman, Senate Judiciary Committee Testimony, Fed. Doc. Clearinghouse at 2 (Feb. 2, 2005)).

13 *See id.* at * 31.

To make matters worse, some of the doctors issued two separate reports based upon the same film; in one report, they reported silicosis; in the other, they reported asbestosis. One article, summarizing the testimony before Judge Jack, also pointed out that:

> The anecdotal testimony from the plaintiffs' B readers themselves helped ensure the finding of unreliability. One diagnosing physician described his involvement as "easy money" for "easy work," although he had never before diagnosed anyone with silicosis. Most of the plaintiffs' witnesses used word-processed language, such that the same diction errors appeared identically in every report from one witness. Many of the witnesses did not write, read, or sign their reports. For some witnesses, their reports included diagnostic language with which they disagreed, but when the screening company insisted, they "capitulated." Some of the witnesses were biased by their compensation, which was greater for finding silicosis than for not finding it.[14]

Ultimately Judge Jack stated that the silicosis diagnoses upon which plaintiffs had filed their lawsuits raised "great red flags of fraud."[15]

Unfortunately, Judge Jack's concerns about "positive B Reads" are not unique.[16] Issues concerning B Reader variability in the litigation context have been

---

14 *See* Schachtman, *supra*, at 7 (internal citations omitted); *see also In Re Silica Products Liab. Lit.*, 2005 WL 1593936 at * 17, 32, 44, 53.

15 *See In re Silica Prods. Liab. Litig., Daubert Hearings*, Feb. 17, 2005, Tr. at 23 (discussing testimony of Dr. Harron.)

16 A recent report by the AEI-Brookings Joint Center for Regulatory Studies discusses in detail the litigation screenings in which certain B Readers have participated. *See* Judyth Pendell, *Regulating Attorney-Funded Mass Medical Screenings: A Public Health Imperative?* (AEI-Brookings Joint Center for Regulatory Studies Sept. 2005), *available at* http://www.aei-brookings.org/publications/abstract.php?pid=993. *See also* Lester Brickman, *On the Theory Class's Theories of Asbestos Litigation: The Disconnect Between Scholarship and Reality?*, 31 PEPP. L. REV. 33 (2004); Roger Parloff, *The $200 Billion Miscarriage of Justice; Asbestos Lawyers are Pitting Plaintiffs Who Aren't Sick Against Companies that Never Made the Stuff and Extracting Billions for Themselves*, FORTUNE, Mar. 4, 2002, at 158, *available at* 2002 WL 2190334; David M. Setter et al., *Why We Have to Defend Against Screened Cases: Now is the Time for a Change*, 18 MEALEY'S LITIG. REP. ASBESTOS (Nov. 12, 2003); Lester Brickman, *Ethical Issues In Asbestos Litigation*, 33 HOFSTRA L. REV. 833 (2005).

documented for many years, with B Readers becoming directly involved in the claimant recruiting process and taking part in screening practices that would never be used in a clinical setting. One of the earliest detailed reviews of these types ofpositive B Reads arose out of the National Tire Workers Litigation Project (NTWLP).[17] The focus there was on litigation screenings performed around the country through x-ray equipment loaded on to mobile vans.[18] Information distributed to tire workers stated that at one location where screenings were conducted, sixty-four percent were positive for asbestosis and at a second location ninety-four percent tested had asbestosis.[19]

In 1982, under collective bargaining agreements between the United Rubber Workers' International Union (URW) and selected rubber companies, a multiphasic medical surveillance program was put in place to benefit its members in the early detection of occupational and non-occupational related conditions.[20] The surveillance program included chest x-ray examinations. After four cycles of examinations the program had failed to detect any excess asbestosis or other pneumoconiotic conditions among tire workers.

In October of 1986, the union requested that NIOSH conduct an evaluation of the occurrence of pneumoconiosis among tire workers to determine if the

---

17 *See Raymark Indus. v. Stemple*, No. 88-1014-K, 1990 WL 72588, * 5 (D. Kan. May 30, 1990).

18 *Id.*

19 *Id.* at 10.

20 *See* J. Jankovic & R. B. Reger, HEALTH HAZARD EVALUATION REPORT, NIOSH Rep. No. HETA 87–017–1949 (Dep't Health & Human Servs., NIOSH, 1989) (citing L. S. Belizcky, *A Fifteen Year Overview of the URW's Activities in Occupational Safety and Health*, Joint URW/JRW Conference, Seattle, Wash., June 1986).

union/industry operated medical surveillance program had missed cases of asbestos-related disease.[21] Focusing on workers with the greatest potential for disease, NIOSH had an independent panel evaluate 987 x-rays from the surveillance program of workers greater than forty years of age. Of the 987 films read by three independent B Readers (who were board certified radiologists), *only* twenty-two of the 1987 films (2.2%) were found to show pleural plaques, a marker of asbestos exposure, and *only* two (0.2%) showed physical changes consistent with asbestosis.[22]

In addition to the NIOSH evaluation, the reported high prevalence of asbestosis among tire workers in the NTWLP was the subject of a peer reviewed article in the medical literature.[23] In that study, 439 chest films from tire workers that had filed legal claims were re-evaluated by three board certified radiologists, who were certified B Readers, in an independent manner using the ILO classification system. Of the 439 originally found to have x-ray changes consistent with asbestos-related disease, the consensus independent interpretation of the three radiologists was that *only* sixteen (3.6%) had either parenchymal and/or pleural changes consistent with an asbestos exposure.[24]

These types of "positive B Reads" have also been subject to judicial scrutiny beyond Judge Jack's recent findings.[25] Judge Charles Weiner, who had presided

---

21 *Id.*

22 *Id.* at 14.

23 *See* R. B. Reger et al., *Cases of Alleged Asbestos-Related Disease: A Radiologic Re-Evaluation,* 32 J. Occupational Med. 1088-90 (1990).

24 *Id.*

25 *See generally,* Victor E. Scwhartz & Leah Lorber, *A Letter to the Trial Judges of America: Help the True Victims of Silica Injuries and Avoid Another Litigation Crisis,* 28 AM. J. TRIAL ADVOC. (2004).

over the federal asbestos MDL, determined "that the filing of mass screening cases is tantamount to a race to the courthouse and has the effect of depleting funds, some already stretched to the limit, which would otherwise be available for compensation to deserving Plaintiffs," and administratively dismissed without prejudice "[a]ll non-malignant asbestos-related personal-injury cases . . . initiated through a mass screening."[26] Another court cited an audit performed in 1998 by the Manville Settlement Trust, which determined that 59% of x-ray readings relied upon by plaintiffs' counsel to show asbestos-related abnormalities were inaccurate.[27]

More recently, researchers at Johns Hopkins University compared the x-ray interpretations of B Readers employed by asbestos plaintiffs' counsel with the subsequent interpretations of six independent B Readers who had no knowledge of the x-rays' origin.[28] The study found that for a group of 492 plaintiffs, the B Readers hired by plaintiffs found asbestos-related lung abnormalities on the x-rays 95.9% of the time, whereas the independent B Readers found such abnormalities on the same x-rays only 4.5% of the time.[29] The study concluded that

---

26 *In re Asbestos Prods. Liab. Litig. (No. VI)*, MDL 875, Admin. Order No. 8, 2002 WL 32151574 (E.D. Pa. Jan. 16, 2002).

27 *In re Joint E. & So. Dists. Asbestos Litig.*, 237 F. Supp. 2d 297, 309 (E.D.N.Y. 2002); *see also* Am. Bar Ass'n Comm'n on Asbestos Litig., *Report to the House of Delegates* 8 (2003) (finding that the rate of findings consistent with prior asbestos exposure generated by litigation screening companies is "startlingly high," often exceeding 50% and sometimes reaching 90%).

28 *See* Joseph N. Gitlin, et al., *Comparison of "B" Readers' Interpretations of Chest Radiographs for Asbestos Related Changes*, 11 ACAD. RADIOLOGY 843 (Aug. 2004).

29 *Id.* at 855.

the magnitude of that difference was "too great to be attributed to inter-observer variability."[30]

And in just the past several months, the litigation screening practices in which NIOSH certified B Readers have participated have come under even further scrutiny. The U.S. Attorney's Office in the Southern District of New York (Manhattan) has convened a federal grand jury to consider possible criminal charges arising out of the federal silica litigation.[31] A judge overseeing the Owens Corning bankruptcy noted that certain pro-plaintiff B Readers were "so biased that their readings [are] simply unreliable." *Owens Corning v. Credit Suisse First Boston*, 322 B.R. 719, 723 (D. Del. 2005). Congress is looking into screening abuses as well. In August 2005, U.S. Rep. Joe Barton (R-TX), Chairman of the House Energy and Commerce Committee, and Oversight and Investigations Subcommittee Chairman Ed Whitfield (R-KY) sent a letter to the plaintiffs' medical experts involved in the silica MDL litigation seeking records and information regarding public health concerns arising from various medical practices conducted in support of that litigation.[32] Finally, the Claims Resolution Management Corporation (which manages the Manville Personal Injury Settlement Trust), the Eagle-Picher Personal Injury Settlement Trust and the Celotex Asbestos Settlement Trust have each

---

30 *Id.* at 852, 843. As one physician has explained, "the chest x-rays are not read blindly, but always with the knowledge of some asbestos exposure and that the lawyer wants to file litigation on the worker's behalf." David E. Bernstein, *Keeping Junk Science Out of Asbestos Litigation*, 31 PEPP. L. REV. 11, 13 (2003) (quoting Lawrence Martin, M.D.).

31 *See* Jonathan D. Glater, *Lawyers Challenged on Asbestos*, N.Y. TIMES, July 20, 2005, at C1, *available at* 2005 WLNR 11332864.

32 *See* Press Release, *Barton, Whitfield Query Physicians Regarding Silicosis*, Aug. 2, 2005, *at* http://energycommerce.house.gov/108/News/08022005_1619.htm.

stated that they will no longer accept reports prepared by the doctors that were the subject of Judge Jack's opinion.[33]

III. Recommendations for B Reader Program Improvements and Ethics of B Readers

As noted above, the primary goals of the NIOSH B Reader program were to (1) reduce the variability of results among x-ray readers, and (2) provide for greater consensus among medical diagnoses by adopting standards and certification requirements. Unfortunately for science and medicine, some B Readers have found staggering numbers of abnormal conditions in workers even, in many cases, where there has only been minimal exposure to pneumoconiotic dusts. Because these positive B Reads come with the "stamp of approval" of a NIOSH–certified physician they are often given credence even though independent studies have shown they cannot withstand scrutiny. Thus, while the NIOSH B Reader program was aimed at reducing variability and increasing the precision of readings, the program is being used to precisely the opposite effect.

As noted above we, believe that while a B Reader Code of Ethics should be developed for certified physicians interpreting chest x-rays for the pneumoconioses, more needs to be done if the abuses described above are to be addressed.

---

[33] *See* Memorandum from David Austern, President of the Claims Resolution Management Corporation (September 12, 2005). *See also* Letter from William B. Nurre, Executive Director Eagle-Picher Personal Injury Settlement Trust, to Claimants' Counsel (October 19, 2005); Notice of Trust Policy Regarding Acceptance of Medical Reports from John L. Mekus, Executive Director of the Celotex Asbestos Settlement Trust (October 20, 2005) (*available at* http://www.celotextrust.com/news_details.asp?nid=22).

A. Establish an Audit Program

NIOSH, as the certifying body, has a duty and obligation to ensure that persons certified use the credential bestowed upon them correctly. NIOSH conducts audits in a separate test and certification program it operates having to do with approval of respiratory protective devices used by workers to minimize exposure to toxic agents in the work environment. To preserve the integrity of the B Reader system, NIOSH should consider a mechanism to audit B Readers as well.

At this point, it is imperative that NIOSH implement an audit program for B Readers engaged in providing interpretations as expert witnesses in litigation and/or compensation programs. A primary incentive for a physician to become certified as a B Reader today apparently is to earn additional income by rendering interpretations for litigation or to serve as an expert medical witness. While still serving a need, the traditional role of a B Reader certification -- reading of chest films for epidemiologic studies, surveillance of dust-exposed workers in the clinical practice of medicine and enforcement of health regulations in the workplace -- has become secondary to its use in litigation and practically unimportant in the context of pneumoconioses radiology.

While the exact characteristics of the program should be worked out by NIOSH and stakeholders, at a minimum NIOSH should consider some type of annual questionnaire to be sent to certified B Readers to determine first if they are engaged in interpreting chest films for purposes of litigation or workers compensation. For those not engaged in such services the questionnaire could be signed and returned. For those engaged, additional responses would be required to

determine such specifics as (1) the types of activity engaged in, (2) the identity of the law firms who have retained their services, (3) the percentage of professional time spent in such activities, fee structure and percentage of professional income, (4) affirmation that fees are not contingent on the outcome of the proceeding, (5) assurance that proper notification of the medical results are being made to those being screened, (6) assurance that any diagnosis is being made on the basis of accepted medical practices (and not solely to satisfy requirements in a legal setting), and (7) affirmation that diagnoses of pneumoconioses are not being rendered based on ILO classification alone. The B Reader would have to sign the questionnaire and attest to the truthfulness of the responses. If not returned, or a B Reader falsifies a report, the certification would be revoked. B Readers would also be required to notify NIOSH at the time they begin receiving compensation for participating in litigation or compensation-related work.

In addition, the chest x-rays used as a basis for establishing the diagnoses of silicosis before Judge Jack reportedly are still in the custody of the United States District Court. NIOSH, in collaboration with the American College of Radiology Committee on Pneumoconioses, should request access to the x-rays in order to conduct a study by independent experts of all of the films included in the litigation (or at least a representative sample thereof) to determine the extent of abnormalities on the films consistent with silicosis or other pneumoconioses. The results of such a study would be useful in determining if those B Readers should be decertified.

Further, NIOSH certified B Readers should also be required to submit to NIOSH the results of chest x-ray interpretations provided for legal and compensation purposes to include data regarding whether parenchymal or pleural changes consistent with the pneumoconioses are present or absent and, if abnormalities are present, to provide details regarding profusion and shape of small opacities, size of large opacities, pleural plaques (site, calcification, extent and width of plaques in profile), and pleural thickening (site, calcification, extent and width of thickening in profile). These reports would be submitted without regard to who had retained the B Reader and without identifying the name or other personal information concerning the claimant. This information may also be useful to NIOSH in crafting additional B Reader guidelines and requirements.

From these reports, NIOSH could create a database of information and, based on a statistical sampling weighted towards B Readers that are interpreting the largest number of films for legal and compensation purposes, seek to obtain the x-rays and have them interpreted by an independent panel of expert B Readers appointed by NIOSH. (Additionally, any pattern of suspicious readings identified by NIOSH could be subjected to having the original x-rays interpreted by the expert panel.) B Readers falling outside acceptable variance limits determined by that panel would have their certification revoked.

Finally, NIOSH should establish a process in which audits of particular B Readers could be requested by third parties.

Should NIOSH not be willing or able to incorporate an audit system into the B Reader Program, then perhaps the program should be discontinued.[34] Researchers and clinicians engaged in dust research and medical surveillance in other countries do not have a similar competency certification program, yet it does not seem to thwart those researchers or those foreign medical communities from advancing the medical understanding and recognition of dust diseases outside the United States. The B Reader certification was developed as a means to control the variability in interpretations of chest x-rays. After thirty years of experience and effort in improving the competence of physicians to interpret films for the pneumoconioses, to the extent we are seeing even great variability among B Readers, particularly in the litigation context, perhaps the program is no longer satisfying its true purpose. NIOSH must ask itself if the only purpose for maintaining this resource intensive program is to provide dueling experts for the courts. If so, the Institute could better use its funds for public health purposes and let the courts devise their own means of establishing the expertise of a physician rendering interpretations as to whether a disease is dust connected.

B. Establish a Panel of Experts in Pneumoconiosis Radiology to Serve as Court Appointed Experts

As courts increasingly deal with complex scientific questions, concerns have been expressed regarding the objectivity and reliability of both plaintiff and defense

---

[34] *See* Glenn, *supra*, at 6.

experts.[35] A survey by the Federal Judicial Center (FJC) asked judges about problems associated with scientific experts. The most frequently cited problem was that, "Experts abandon objectivity and become advocates for the side that hired them."[36]

Under Rule 706 of the Federal Rules of Evidence, judges have the authority to use court-appointed experts, even without the consent of the parties.[37] A survey by the FJC found that 87 percent of the judges believed that in some cases it would be useful to appoint their own independent experts but only 20 percent had ever appointed an expert. One reason given for not using court-appointed experts was the lack of a procedure for locating scientists that are both independent and knowledgeable.[38]

NIOSH should consider appointing a truly independent Panel of Experts in Pneumoconiosis Radiology to act as court-appointed experts to interpret and advise on chest films, and the results of other roentgenographic procedures admitted in to court proceedings. Through its long term relationship with the Committee on Pneumoconioses of the American College of Radiology, NIOSH should impanel a preeminent group of radiologists and chest physicians certified as NIOSH B Readers to assist the courts. Factors to consider in appointments would be demonstrated independence by presently not engaging as an expert in litigation,

---

35 *See Court Appointed Scientific Experts,* A Handbook for Experts, American Association for the Advancement of Science, Washington, (2002) at 6, available at http://case.aaas.org/handbook.pdf (last visited Dec. 28, 2005)

36 *Id.*

37 *Id.*

academic standing and appointments, publications in the field of pneumoconioses radiology, experience in interpreting large numbers of chest x-rays for the pneumoconioses through medical surveillance and other programs, and recognized professional standing in the appropriate medical societies.[39]

C. Specific Considerations for the B Reader Code of Ethics

The two comments of this subsection address specific subject matter in the the NIOSH proposed "Ethical Considerations for B Readers."[40]

1. Communication of Abnormal Conditions

An ethical consequence of B Readers interpreting chest x-rays in the medical-legal setting that NIOSH should consider is just how subjects are notified about abnormal findings.[41] When working with third-parties to interpret chest x-rays as an expert witness, B Readers need to determine if -- according to the law in the state they practice -- such arrangements constitute a physician-patient relationship and whether any duty to communicate findings to the individual are established. In cases where a physician-patient relationship is not established, B Readers should still apprise themselves of the procedures by which the third party will inform

---

(...continued)

38 *Id.*

39 *See also* Griffin Bell, *Asbestos Litigation and Judicial Leadership The Courts Duty to Help Solve the Asbestos Litigation Crisis*, National Legal Center for the Public Interest Perspectives on Legislation, Regulation and Litigation, Vol. 6, No. 6 at 36-37 (2002). For a more detailed discussion of the potential use of independent medical panels, *see* Pendell, *supra* note 17, at 39.

40 NIOSH Safety and Health Topic: Chest Radiography, "Ethical Considerations for B Readers", <http://www.cdc.gov/niosh/topics/chestradiography/breader-ethics.html> (last visited December 21, 2005).

41 *See* Leonard Berlin, *Are Radiologists Contracted by Third Parties to Interpret Radiographs Liable for Not Communicating Results Directly to Patients*, 178 AM. J. OF RADIOLOGY 27 (2002).

individuals and ensure themselves that communication takes place in an ethical manner that is sensitive to the individual. This issue and its impact on plaintiffs' in litigation was troubling to Judge Jack:

> Then there is the toll taken on the misdiagnosed Plaintiffs. If these Plaintiffs truly have abnormal x-rays, then the radiographic findings may be caused by a number of conditions other than silicosis. And when the diagnosing doctors fail to exclude these other conditions, it leaves the Plaintiffs at risk of having treatable conditions go undiagnosed and untreated.
>
> In the case of the Plaintiffs who are healthy, at least some of them can be expected to have taken their diagnoses seriously. They can be expected to have reported the diagnoses when applying for health insurance and life insurance – potentially resulting in higher premiums or even the denial of coverage altogether. They can be expected to report the diagnoses to their employers and to the Social Security Administration. And they can be expected to report the diagnoses of this incurable disease to their families and friends.
>
> These people have been told that they have a life-threatening condition: but they are not told by a doctor; they are told by a lawyer--apparently in most cases through the mail. In most cases, they never saw the doctor who diagnosed them. And in most cases, they never had the opportunity to ask the diagnosing doctor questions about the diagnosis and what it means. When dealing with this MDL and its 10,000 Plaintiffs, it is easy to forget that "statistics are human beings with the tears wiped off." (Feb. 18, 2005 Trans. at 252 (quoting Dr. Irving Selikoff).) But it should not be forgotten that a misdiagnosis potentially imposes an emotional cost on the Plaintiff and the Plaintiff's family that no court can calculate. [42]

---

42 *See In re Silica Prods. Liab. Litig.*, 2005 WL 1593936 at * 60-61.

NIOSH should require assurance that B Readers that are interpreting chest x-rays for compensation programs or for litigation purposes, are providing the results of their interpretations to the claimants in a medically accepted manner so that those claimants have the opportunity for appropriate medical counseling and follow-up. To the extent that B Readers are providing their interpretations to another medical professional for diagnostic purposes, the B Reader should be requested to take steps to ensure that the other medical professional have undertaken similar safeguards.

2. "Clinical" versus "Legal" Diagnoses

NIOSH needs to be aware that some B Readers distinguish between a "clinical" diagnosis and a "legal diagnosis." One B Reader active in the litigation process, Dr. Ray Harron testified as follows about his "diagnosing" process:

> [I]f there's a history of exposure with some latency and then I've got an x-ray, then I can tie it together and say 'within a reasonable degree of medical certainty' this individual has whatever pneumoconiosis I think it is. And 'within a reasonable degree of medical certainty,' it is my understanding that all the lawyers on both sides of this room agree means better than a 50 percent chance that this is what the diagnosis is. It's not a diagnosis the way a treating physician would have to make a diagnosis.... [43]

Dr. Harron explained that based upon diagnoses "to a reasonable degree of medical certainty," he would not "put [the clients] on drugs, do radiation therapy, put radium in them, [or] refer them to a surgeon for some kind of invasive work."[44]

---

43 *See In re Silica Prods. Liab. Litig., Daubert Hearings*, Feb. 16, 2005, Tr. at 267-268 (testimony of Dr. Harron).

44 *See id.* at 305-08.

Stated differently, Dr. Harron appeared to treat "reasonable degree of medical certainty" as "a legal standard and not a real diagnosis."[45]

The current draft of the B Reader Code of Ethics contains a code that reads: "B Readers shall recognize the limitations of chest radiograph classifications, and shall not make clinical diagnoses based on chest radiograph classifications alone.[46]" The code should make clear (1) that whether or not a physician-patient relationship has been established is not dependant upon the setting ("clinical" vs. "legal"), and (2) that "diagnoses" of any kind, especially for litigation or compensation purposes, are not to be made on the basis of a chest x-ray alone.[47]

IV. Conclusion

It is clear that the original purpose of the B Reader program -- to serve as a unique quality assurance program -- has been completely overtaken by its use in the medical-legal setting. While it is a shared responsibility of the courts, state medical licensing boards, and professional medical societies to maintain integrity in expert medical testimony, it is imperative that NIOSH, as the agency that certifies the competence of B Readers, take steps to protect the respectability of its certification. While the ethical guidelines are an important first step, NIOSH can and should do much more to make sure that original goals of the B Reader program are achieved.

---

45 *See id.* at 268; *see also id.* at 305-08.

46 NIOSH "Ethical Considerations of B Readers," *supra*, ¶ 3.

47 *See* Ross, *supra*, at 1120-28.

SUBMISSION OF THE COALITION FOR LITIGATION JUSTICE, INC., AMERICAN INSURANCE ASSOCIATION, NATIONAL ASSOCIATION OF MANUFACTURERS, NATIONAL FEDERATION OF INDEPENDENT BUSINESS LEGAL FOUNDATION, NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS, PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA, NATIONAL ASSOCIATION OF MUTUAL INSURANCE COMPANIES, AMERICAN TORT REFORM ASSOCIATION, AND INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION IN RESPONSE TO THE REQUEST FOR COMMENTS ON NIOSH'S DRAFT "RECOMMENDATIONS FOR APPLYING THE INTERNATIONAL LABOUR OFFICE (ILO) INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSES IN MEDICAL DIAGNOSIS, RESEARCH AND POPULATION SURVEILLANCE, WORKER HEALTH MONITORING, GOVERNMENT PROGRAM ELIGIBILITY, AND COMPENSATION SETTINGS"

I. Page 1, sentence beginning at line 14:

As NIOSH notes in its November 17, 2005 Federal Register announcement inviting comments on the use of the ILO classification system by NIOSH B Readers, the proceedings in the federal silica MDL in the U.S. District Court for the Southern District of Texas raised serious questions regarding the ethical conduct of NIOSH certified B Readers in diagnosing cases of silicosis. The conduct of certain NIOSH certified B Readers has also been a problem for many years in connection with litigation involving alleged exposures to asbestos. It is undisputed that the B Reader certification has become of primary importance in litigation involving asbestos and silica and, unfortunately, is of secondary importance for research purposes, worker health surveillance, and medical diagnosis in the regulatory setting. Yet the draft recommendations do not address the application of the ILO system in litigation by B Readers. NIOSH should redraft the recommendations with guidance for application in the legal setting and re-post for additional comments from affected parties.

II. Page 1, sentence beginning at line 33:

NIOSH should cite to references regarding the controversial use of the ILO system in the non-research setting.

III. Page 1, issue 5) at line 43:

We support the use of quality control films for "calibrating" readers in order to classify films in a more consistent and precise manner mentioned here and elsewhere in the document. We are not aware of a set, or sets, of films that demonstrate the patterns consistent with the pneumoconioses that could be used for this purpose. It would seem that only researchers in academia involved in reading large numbers of films for the pneumoconioses with access to large film archives would be able to develop such a practical tool. If such "calibration sets" are not available, this would seem a worthwhile project for NIOSH to pursue (perhaps in

collaboration with the Committee on Pneumoconioses of the American College of Radiology), that once developed could be produced in quantity and purchased from the institute and serve to improve the variability of readers. We urge NIOSH to allocate necessary funds from its research budget to the development of standard sets of "calibration" films for utilization in quality assurance of readings by B Readers and others interpreting chest x-rays according to the ILO System.

IV. Page 2, paragraph at line 16:

We are confused as to the purpose and inclusion of this paragraph. We recognize that this guidance will be posted on the NIOSH web site where the general public will have access, but it seems the intent and purpose of the guidance is for applying the ILO Classification System by medical professionals, researchers, compensation benefits administrators and others using the ILO Classification System in each of the five topic areas addressed in the recommendations. The paragraph is written for dust-exposed workers experiencing symptoms on how to find appropriate medical care. Of course this is well intentioned but we fail to see how seeking medical care for symptoms relates to the application of the ILO Classification System.

V. Page 5 at line 2:

We do not understand why "Population Surveillance" is included in this section. The guidance in the section seems intended for application of the ILO System in research. This section does not appear to offer any guidance for application of the ILO System in population surveillance. It would seem that population surveillance is more associated with medical surveillance of workers or worker health monitoring. Indeed, the next major section on worker health monitoring has a subsection entitled, "Use of health monitoring data for population surveillance purposes." Perhaps the title of this section should be revised.

VI. Page 6, paragraph at line 9:

As discussed above, we strongly support and encourage NIOSH to develop set(s) of "calibration" films to be used for quality assurance purposes to control reader "drift" and dishonest interpretations from being provided in the use of the ILO System by B Readers.

VII. Page 13, lines 7-14:

We agree that the ILO System should not be used to determine impairment and establish compensation payments. However, as a useful reference for those needing information on evaluating impairment of the respiratory system, we

recommend NIOSH reference Chapter 5, of the AMA Guides for the Evaluation of Permanent Impairment.

VIII. Page 14, paragraph at line 26:

Again, we strongly encourage NIOSH to develop set(s) of "calibration" films to be used for quality assurance purposes to control reader "drift" and dishonest interpretations from being provided in the use of the ILO System by B Readers.

Dr. Jerome F. Wiot
Professor Emeritus
Department of Radiology
University of Cincinnati Medical Center
Cincinnati, Ohio
(513) 475-8763

Please see attached from Dr. Jerome F. Wiot, Professor Emeritus, Department of Radiology, University of Cincinnati Medical Center, Cincinnati, Ohio. **(see attached)**

Wolfe, Anita L.

From: Nancy Hudson [hudsonnr@covad.net]
Sent: Friday, January 13, 2006 5:15 PM
To: Coal Workers' Health Surveillance Program, NIOSH
Subject: Comment on B Reading Ethics
Attachments: comment on b reading ethics.doc

Please see attached from [redacted], Professor Emeritus, Department of Radiology, University of Cincinnati Medical Center, Cincinnati, Ohio.

For questions, please contact Dr. Wiot at (513) 475-8763.

Thank you.

Jerome F. Wiot, M.D., Inc.

222 Piedmont Avenue, Suite 2100, Cincinnati, Ohio 45219
Voice Mail: 513-825-0062
Fax: 513-475-8038
E-mail: hudsonnr@covad.net

NIOSH
CWHSP@cdc.gov

Comment on B Reading Ethics

Gentlemen:

This is comment for the record on your draft document "Ethical Considerations for B Readers" as referenced in 70FR6976 and published on 17 November 2005.

I have been involved in your coal miner surveillance and other programs since 1970. Along with my then chairman, Ben Felson, I was a charter member of the American College of Radiology Task Force on Pneumoconiosis and I remain a consultant and lecturer for that group. I succeeded to the chairmanship of the Task Force for several years. I also have been a member of the ILO working group on its chest classification and served as co-chairman of the effort to devise ILO 2000, which you now have promulgated. In addition, I helped to create and validate the B reader program and have maintained my status as a B reader since the program's inception. I also was a chancellor and president of the American College, and a trustee and president of the American Board of Radiology. All of this is to qualify my opinion, which as stated below represents my thoughts and not those of any organization of which I am a part.

In recent years, the B reader program has come under considerable criticism because it has become clear in several ways that some physicians who have qualified themselves as B readers have then applied their skills in a manner which betrays the intent of the program. The Daubert hearing by federal Judge Janis Jack and the 2004 paper by Gitlin, et al in Academic Radiology are but two examples of the way at least a few physicians with technical skills can pervert those skills.

When we helped to create your B reader program, the intent was to provide NIOSH with a panel of readers whose competence was supported by their ability to classify chest radiographs according to the ILO system with a degree of consistency. Despite its misuse, the B reader program is the only credential recognized in this country and world-wide as meaningful. None of us who were involved thought at the time that we would see the uses to which your credentials have been put by those whom Judge Jack and others have termed fraudulent. So you are correct in attempting to improve the program to avert further misuses, rather than abandoning it, as some critics have urged. Codes of medical ethics are as old as the profession of medicine and their promulgation and enforcement by professional societies is one of the reasons that medicine aspires to be more than a trade or vocation. There was a time when medical societies took action against members who were found to violate codes of ethics in a manner that protected the public against the violators. However, when the US Supreme court in Goldfarb vs Virginia State Bar ruled that professional societies were liable for antitrust violations, the teeth were pulled from medical society codes of ethics. Codes became aspiration rather than

enforceable statements of propriety. Further, codes could be applied only against physicians who were members of a society promulgating the code. Since physicians practice on the basis of state licensure and specialty board certification, their membership status is not a governing factor with licensing boards of health insurance programs.

The promulgation of a code of ethics by a Public Health Service agency may be unprecedented. Unless the promulgation of the code is accompanied by programmatic change which would deprive an offending physician of the right to claim B readership, I fear that such a code as you propose would have no deterrent effect on abusers of the B reader credential. Thus, I find no real fault with your draft language. But I urge that you go beyond the code with amendments in your regulations to purge those physicians who overtly violate the intent.

As the program has existed, NIOSH offers the periodic qualifying examinations and recertification examinations to those physicians who wish to take them. Those who pass are then listed as B readers and can sell their services as such. To my knowledge, you have no method of tracking the performance of anyone with a B reader certificate. Indeed, the diminishing number of physicians choosing to maintain B reader status is likely a reflection of the posture of some plaintiffs' attorneys in using only a small group of B readers whose attitude was characterized by one of the group as "I never got a normal chest film from a lawyer."

Thus, I join at least a few other commenters in urging that you promulgate your ethical code and that you go beyond it to create a surveillance program which would allow the detection and verification of abuse of your system.

I suggest several elements of what should be a workable program to provide a basis for acting against those accused and found guilty of misusing the ILO system and your B reader qualification. Some of this would require amending your regulations, but none should require legislative change.

The first step would be to require anyone passing the test and accepting B reader standing to agree in advance to furnish copies of films and B readings upon NIOSH demand.

NIOSH would make such as request only upon receipt of a valid compliant against a B reader. Such a complaint would trigger a letter from NIOSH to the B reader asking for a list of all of the B readings performed during the current certification period. From that list, NIOSH could select a sample and demand that the accused B reader retrieve the films and B readings from his clients for submission to NIOSH. Failure to comply with this requirement within a reasonable time would, of itself, be grounds for cancellation of B reader status.

When the requested films and readings are received, NIOSH should conduct a blinded reading trial using several B readers who are consultants to NIOSH and determine the extent of the difference between the readings of the initial B reader and those of the NIOSH consultants. If the pattern of discrepancies is in excess of normal inter-reader variations, then NIOSH could

advise the accused B reader of its intention to revoke his status. If the agency chooses to allow an appeal, a protocol should be developed for that.

While this represents a relatively painstaking process, it would provide a strong basis for NIOSH revocation of B reader status if carried through. My guess is that the promulgation of this program and the first few instances of its application would be sufficient to show that the B reader system now has teeth and that they can be used.

When the 1969 Coal Mine Health and Safety Act created the NIOSH program and subsequently the B reader element, a question for the US planners was whether to follow the pattern in Britain and Germany and use a small group of government-employed radiologists who did nothing but read chest films or whether to make the new program part of the health care community. NIOSH opted for the second course. That decision has had many values. Current criticism of the actions of a few B readers and the inability of NIOSH to do anything about them can be answered by adopting a program such as I have outlined above.

I am proud of the efforts I contributed to the NIOSH programs over three decades. From the beginning NIOSH supported improving the skills of radiologists and other physicians, improving the quality of chest radiography and integrating this program into the health care of workers in dusty environments.

I salute you on your intents to fix the B reader system, rather than scrapping it.

Sincerely,

Jerome F. Wiot, M.D.
Emeritus Professor
Department of Radiology
JFW: nh

Mark G. Ellis
President
Industrial Minerals Association - North America
National Industrial Sand Association
2011 Pennsylvania Avenue, NW, Suite 301
Washington, DC 20006
(202) 457-0200
(202) 457-0287 (Fax)
markellis@ima-na.org
markellis@sand.org

See attached.

Wolfe, Anita L.

From: Mark Ellis [markellis@ima-na.org]

Sent: Tuesday, January 17, 2006 1:20 PM

To: Coal Workers' Health Surveillance Program, NIOSH

Cc: markellis@sand.org

Subject: NISA Comments to NIOSH on ILO & B Readers

Attachments: NISA Comments (01-17-06).pdf; DC-128493-v1-Coalition_et_al__NIOSH_Submission_1_13_06.doc; 2695232_NIOSH_Recommendations_for_Applying_the_ILO_Systeml.doc.doc

Hard copy of comments to follow in the mail.

We've moved our office effective November 23!

Please note our new address and telephone numbers:

Mark G. Ellis
President
Industrial Minerals Association - North America
National Industrial Sand Association
2011 Pennsylvania Avenue, NW, Suite 301
Washington, DC 20006
(202) 457-0200
(202) 457-0287 (Fax)
markellis@ima-na.org
markellis@sand.org

NATIONAL INDUSTRIAL SAND ASSOCIATION

2011 PENNSYLVANIA AVENUE, NW • SUITE 301 • WASHINGTON, DC 20006

Telephone: (202) 457-0200
Fax: (202) 457-0287
www.sand.org

January 17, 2006

David N. Weissman, MD
CDC/NIOSH
Division of Respiratory Disease Studies
Mailstop H-2900
1095 Willowdale Road
Morgantown, WV 26505

Dear Dr. Weissman:

In response to the Notice of Public Input Opportunity published in the *Federal Register* on November 17, 2005, 70 FR 69765-66, the National Industrial Sand Association (NISA) is pleased to offer the following comments on two documents proposed by the National Institute for Occupational Safety and Health (NIOSH), namely, "*Recommendations for Applying the International Labour Office (ILO) International Classification of Radiographs of Pneumoconioses in Medical Diagnosis, Research and Population Surveillance, Worker Health Monitoring, Government Program Eligibility, and Compensation Settings*" and "*Ethical Considerations for B Readers.*"

By way of background, NISA is a trade association organized to advance the interests of companies that mine or process industrial sand. NISA was formed in 1936, and its membership consists of North American industrial sand companies. For its members, NISA addresses such issues as silicosis prevention, safety and health among member company employees, governmental affairs, engineering and technology, membership, communications, transportation and human resources. NISA's silicosis prevention program, one of the few industry programs of its kind, aims to eliminate silicosis among all workers at member companies.

NISA previously has communicated its views to NIOSH on the B Reader program and use of the ILO system for the classification of chest radiographs through oral testimony and written comment. NISA has reviewed the written comments on the above-referenced documents submitted by the Coalition for Litigation Justice, Inc., American Insurance Association, National Association of Manufacturers, National Federation of Independent Business Legal Foundation, National Association of Wholesaler-Distributors, Property Casualty Insurers Association of America, National Association of Mutual Insurance Companies, American Tort Reform Association, and International Safety Equipment Association (see attached). NISA is pleased to

see that others share similar perspectives and concerns. Consequently, NISA wishes to communicate to NIOSH its support and endorsement of the comments submitted by these organizations. It hereby incorporates their comments by reference as its own.

Thank you in advance for considering NISA's public input. Please do not hesitate to contact me should you have any questions regarding this, or any other, matter.

Sincerely,

Mark G. Ellis
President

Attachments

COALITION FOR LITIGATION JUSTICE, INC., AMERICAN INSURANCE ASSOCIATION, NATIONAL ASSOCIATION OF MANUFACTURERS, NATIONAL FEDERATION OF INDEPENDENT BUSINESS LEGAL FOUNDATION, NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS, PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA, NATIONAL ASSOCIATION OF MUTUAL INSURANCE COMPANIES, AMERICAN TORT REFORM ASSOCIATION, AND INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION'S COMMENTS ON NIOSH'S PROPOSED "ETHICAL CONSIDERATIONS FOR B READERS"

The Coalition for Litigation Justice, Inc., American Insurance Association, National Association of Manufacturers, National Federation of Independent Business Legal Foundation, National Association of Wholesaler-Distributors, Property Casualty Insurers Association of America, National Association of Mutual Insurance Companies, American Tort Reform Association, and International Safety Equipment Association are pleased to offer the following comments on the National Institute for Occupational Safety and Health (NIOSH)'s proposed "Ethical Considerations for B Readers." As discussed below, we believe that while a B Reader Code of Ethics is an important step, much more needs to be done if NIOSH is going to address the significant problems posed by the participation of NIOSH-certified B Readers, in mass litigation screenings used to generate tens of thousands of unwarranted asbestos and silica lawsuits.

I. History of the NIOSH B Reader Program

The NIOSH B Reader Program came about when the Black Lung Benefit Act of 1972[1] created a demand for physicians that could interpret conventional chest x-rays for changes consistent with coalworkers' pneumoconiosis.[2] A 1973 study of chest x-ray interpretations from a medical surveillance program for coalworkers' administered by NIOSH found that the level of interreader variability was unacceptable even when using the International Labor Office (ILO) System for Classification of Radiographs for the Pneumoconioses.[3] The B Reader Program was established to reduce the level of variability among readers interpreting chest x-rays by objectively documenting proficiency in evaluating the characteristics and patterns of images on the chest x-ray for occupationally related lung disease.[4]

Since its inception, the NIOSH B Reader Program has attained high visibility in the United States and throughout the world. It continues to have important uses in dust-disease research, in surveillance of dust-exposed workers, in the clinical practice of medicine, and in certain workplace regulations. Unfortunately, however, and through no fault of NIOSH, its use in disease compensation programs, and most notably in litigation involving asbestos and silica, has resulted in widespread abuses that only appear to be increasing over time.[5]

---

1 Black Lung Benefits Act of 1972, Pub. L. No. 92-303, 86 Stat. 150 (1972) (codified at 30 U.S.C. §§ 901 *et seq.*).

2 *See* Robert Glenn, *The NIOSH B Reader Program: Recalling Its True Purpose*, 16 PRODS. LIAB. 1, 3 (ABA, Sec. of Litig., Comm. on Prods. Liab. Litig.) (Winter 2005).

3 *See* Benjamin Felson, et al., *Observations on the Results of Multiple Readings of Chest Films in Coal Miners' Pneumoconiosis*, 109 RADIOLOGY 19, 23 (1973).

4 Glenn, *supra*, at 3.

5 *Id. See also* Nathan Schachtman, *Silica Litigation: Screening, Scheming & Suing*, Washington Legal Foundation, Critical Legal Issues, Working Paper Series No. 135 (November 2005).

II. A Serious Problem Has Emerged

As NIOSH notes in its November 17, 2005 Federal Register announcement,[6] a recent decision by Judge Janis Graham Jack of the United States District Court for the Southern District of Texas raised serious questions regarding the ethical conduct of certain physicians, including NIOSH certified B Readers, in diagnosing cases of silicosis. Of seven physicians singled out by the Judge in her ruling on the reliability of those diagnoses -- under the guidelines set forth by the United States Supreme Court in *Daubert v. Merrell Dow. Pharm., Inc.*, 509 U.S. 579 (1993) -- five were certified NIOSH B Readers.

The problem, as Judge Jack noted in her opinion, is that positive B Reads, come with the stamp of approval of a NIOSH-certified physician and are often considered proof positive of a diagnosis[7] even though it is universally accepted in the medical profession that a chest x-ray alone is not diagnostic of a pneumoconiosis.[8] The silicosis diagnoses upon which the silica suits had been filed rested primarily upon a positive ILO classification. As Judge Jack noted,

> some of the Plaintiffs' lawyers and even the doctors seemed to enter the Daubert hearings under the impression that a positive B-read is a talisman that would dispel any doubts about the diagnoses as a whole.[9]

But while these doctors were able to pass the difficult B Reader examination, by consistently and accurately interpreting chest films according to the ILO system, when they applied this classification system in the silica litigation context, they misread the films to advance the litigation interests of the claimants.[10] Indeed, one

---

6 *See Federal Register,* Vol. 70, No. 221, Thurs., Nov. 17, 2005, 69765, 69766.

7 *See In re Silica Prods. Liab. Litig.*, No. MDL 1553, 2005 WL 1593936 at * 51 (S.D. Tex. June 30, 2005).

8 *See, e.g.* Robert M. Ross, *The Clinical Diagnosis of Asbestosis in This Century Requires More Than a Radiograph,* 124 CHEST 1120-28, 2003.

9 *See In re Silica Prods. Liab. Litig.*, 2005 WL 1593936, at *51.

10 *See* Schachtman, *supra*, at 6. *See also In re Silica Prods. Liab. Litig.*, 2005 WL 1593936, at *53-54.

of the most remarkable statistics presented to Judge Jack was that over 6,000 of the 10,000 silicosis plaintiffs before her had also filed asbestos-related claims.[11] According to the medical experts who testified, the number of silica claimants who also had made an asbestos-related claim was "stunning and not scientifically plausible."[12] Judge Jack ultimately concluded that "a golfer is more likely to hit a hole-in-one than an occupational medicine specialist is to find a single case of both silicosis and asbestosis."[13]

To make matters worse, some of the doctors issued two separate reports based upon the same film; in one report, they reported silicosis; in the other, they reported asbestosis. One article, summarizing the testimony before Judge Jack, also pointed out that:

> The anecdotal testimony from the plaintiffs' B readers themselves helped ensure the finding of unreliability. One diagnosing physician described his involvement as "easy money" for "easy work," although he had never before diagnosed anyone with silicosis. Most of the plaintiffs' witnesses used word-processed language, such that the same diction errors appeared identically in every report from one witness. Many of the witnesses did not write, read, or sign their reports. For some witnesses, their reports included diagnostic language with which they disagreed, but when the screening company insisted, they "capitulated." Some of the witnesses were biased by their compensation, which was greater for finding silicosis than for not finding it.[14]

---

11 *In re Silica Prods. Liab. Litig.*, 2005 WL 1593936, at *31, 53. *See also* David Hechler, *Silica Plaintiffs Suffer Setbacks: Broad Effects Seen in Fraud Allegations*, NAT'L L. J., Feb. 28, 2005, at 18.

12 *See In re Silica Prods. Liab. Litig.*, 2005 WL 1593936, at *53 (quoting Dr. John Parker, former administrator of NIOSH's B reader program); *see also id.* ("[I]n the cases that I've had pathology to evaluate, I have never seen cases in which there was both silicosis and asbestosis in the same patient.") (quoting Dr. Hammar); *id.* ("Even in China, where I saw workers with jobs involving high exposure to asbestos and silica . . . , I did not see anyone or review chest radiographs of anyone who had both silicosis and asbestosis.") (quoting Dr. David Weill, Senate Judiciary Committee Testimony, Fed. Doc. Clearinghouse at 4 (Feb. 3, 2005)); *id.* ("Among the thousands of chest x-rays which I reviewed in asbestos and silica exposed individuals, I cannot remember a single chest x-ray which showed clear-cut findings of both asbestos exposure and silica exposure.") (quoting Dr. Theodore Rodman, Senate Judiciary Committee Testimony, Fed. Doc. Clearinghouse at 2 (Feb. 2, 2005)).

13 *See id.* at * 31.

14 *See* Schachtman, *supra*, at 7 (internal citations omitted); *see also In Re Silica Products Liab. Lit.*, 2005 WL 1593936 at * 17, 32, 44, 53.

Ultimately Judge Jack stated that the silicosis diagnoses upon which plaintiffs had filed their lawsuits raised "great red flags of fraud."[15]

Unfortunately, Judge Jack's concerns about "positive B Reads" are not unique.[16] Issues concerning B Reader variability in the litigation context have been documented for many years, with B Readers becoming directly involved in the claimant recruiting process and taking part in screening practices that would never be used in a clinical setting. One of the earliest detailed reviews of these types ofpositive B Reads arose out of the National Tire Workers Litigation Project (NTWLP).[17] The focus there was on litigation screenings performed around the country through x-ray equipment loaded on to mobile vans.[18] Information distributed to tire workers stated that at one location where screenings were conducted, sixty-four percent were positive for asbestosis and at a second location ninety-four percent tested had asbestosis.[19]

In 1982, under collective bargaining agreements between the United Rubber Workers' International Union (URW) and selected rubber companies, a multiphasic medical surveillance program was put in place to benefit its members in the early detection of occupational and non-occupational related conditions.[20] The

---

15 *See In re Silica Prods. Liab. Litig., Daubert Hearings*, Feb. 17, 2005, Tr. at 23 (discussing testimony of Dr. Harron.)

16 A recent report by the AEI-Brookings Joint Center for Regulatory Studies discusses in detail the litigation screenings in which certain B Readers have participated. *See* Judyth Pendell, *Regulating Attorney-Funded Mass Medical Screenings: A Public Health Imperative?* (AEI-Brookings Joint Center for Regulatory Studies Sept. 2005), *available at* http://www.aei-brookings.org/publications/abstract.php?pid=993. *See also* Lester Brickman, *On the Theory Class's Theories of Asbestos Litigation: The Disconnect Between Scholarship and Reality?*, 31 PEPP. L. REV. 33 (2004); Roger Parloff, *The $200 Billion Miscarriage of Justice; Asbestos Lawyers are Pitting Plaintiffs Who Aren't Sick Against Companies that Never Made the Stuff and Extracting Billions for Themselves*, FORTUNE, Mar. 4, 2002, at 158, *available at* 2002 WL 2190334; David M. Setter et al., *Why We Have to Defend Against Screened Cases: Now is the Time for a Change*, 18 MEALEY'S LITIG. REP. ASBESTOS (Nov. 12, 2003); Lester Brickman, *Ethical Issues In Asbestos Litigation*, 33 HOFSTRA L. REV. 833 (2005).

17 *See Raymark Indus. v. Stemple*, No. 88-1014-K, 1990 WL 72588, * 5 (D. Kan. May 30, 1990).

18 *Id.*

19 *Id.* at 10.

20 *See* J. Jankovic & R. B. Reger, HEALTH HAZARD EVALUATION REPORT, NIOSH Rep. No. HETA 87-017-1949 (Dep't Health & Human Servs., NIOSH, 1989) (citing L. S. Belizcky, *A Fifteen*

(continued...)

surveillance program included chest x-ray examinations. After four cycles of examinations the program had failed to detect any excess asbestosis or other pneumoconiotic conditions among tire workers.

In October of 1986, the union requested that NIOSH conduct an evaluation of the occurrence of pneumoconiosis among tire workers to determine if the union/industry operated medical surveillance program had missed cases of asbestos-related disease.[21] Focusing on workers with the greatest potential for disease, NIOSH had an independent panel evaluate 987 x-rays from the surveillance program of workers greater than forty years of age. Of the 987 films read by three independent B Readers (who were board certified radiologists), *only* twenty-two of the 1987 films (2.2%) were found to show pleural plaques, a marker of asbestos exposure, and *only* two (0.2%) showed physical changes consistent with asbestosis.[22]

In addition to the NIOSH evaluation, the reported high prevalence of asbestosis among tire workers in the NTWLP was the subject of a peer reviewed article in the medical literature.[23] In that study, 439 chest films from tire workers that had filed legal claims were re-evaluated by three board certified radiologists, who were certified B Readers, in an independent manner using the ILO classification system. Of the 439 originally found to have x-ray changes consistent with asbestos-related disease, the consensus independent interpretation of the three radiologists was that *only* sixteen (3.6%) had either parenchymal and/or pleural changes consistent with an asbestos exposure.[24]

(...continued)

Year Overview of the URW's Activities in Occupational Safety and Health, Joint URW/JRW Conference, Seattle, Wash., June 1986).

21 *Id.*

22 *Id.* at 14.

23 *See* R. B. Reger et al., *Cases of Alleged Asbestos-Related Disease: A Radiologic Re-Evaluation,* 32 J. Occupational Med. 1088-90 (1990).

24 *Id.*

These types of "positive B Reads" have also been subject to judicial scrutiny beyond Judge Jack's recent findings.[25] Judge Charles Weiner, who had presided over the federal asbestos MDL, determined "that the filing of mass screening cases is tantamount to a race to the courthouse and has the effect of depleting funds, some already stretched to the limit, which would otherwise be available for compensation to deserving Plaintiffs," and administratively dismissed without prejudice "[a]ll non-malignant asbestos-related personal-injury cases . . . initiated through a mass screening."[26] Another court cited an audit performed in 1998 by the Manville Settlement Trust, which determined that 59% of x-ray readings relied upon by plaintiffs' counsel to show asbestos-related abnormalities were inaccurate.[27]

More recently, researchers at Johns Hopkins University compared the x-ray interpretations of B Readers employed by asbestos plaintiffs' counsel with the subsequent interpretations of six independent B Readers who had no knowledge of the x-rays' origin.[28] The study found that for a group of 492 plaintiffs, the B Readers hired by plaintiffs found asbestos-related lung abnormalities on the x-rays 95.9% of the time, whereas the independent B Readers found such abnormalities on the same x-rays only 4.5% of the time.[29] The study concluded that

---

25 *See generally*, Victor E. Schwartz & Leah Lorber, *A Letter to the Trial Judges of America: Help the True Victims of Silica Injuries and Avoid Another Litigation Crisis*, 28 AM. J. TRIAL ADVOC. (2004).

26 *In re Asbestos Prods. Liab. Litig. (No. VI)*, MDL 875, Admin. Order No. 8, 2002 WL 32151574 (E.D. Pa. Jan. 16, 2002).

27 *In re Joint E. & So. Dists. Asbestos Litig.*, 237 F. Supp. 2d 297, 309 (E.D.N.Y. 2002); *see also* Am. Bar Ass'n Comm'n on Asbestos Litig., *Report to the House of Delegates* 8 (2003) (finding that the rate of findings consistent with prior asbestos exposure generated by litigation screening companies is "startlingly high," often exceeding 50% and sometimes reaching 90%).

28 *See* Joseph N. Gitlin, et al., *Comparison of "B" Readers' Interpretations of Chest Radiographs for Asbestos Related Changes*, 11 ACAD. RADIOLOGY 843 (Aug. 2004).

29 *Id.* at 855.

the magnitude of that difference was "too great to be attributed to inter-observer variability."[30]

And in just the past several months, the litigation screening practices in which NIOSH certified B Readers have participated have come under even further scrutiny. The U.S. Attorney's Office in the Southern District of New York (Manhattan) has convened a federal grand jury to consider possible criminal charges arising out of the federal silica litigation.[31] A judge overseeing the Owens Corning bankruptcy noted that certain pro-plaintiff B Readers were "so biased that their readings [are] simply unreliable." *Owens Corning v. Credit Suisse First Boston*, 322 B.R. 719, 723 (D. Del. 2005). Congress is looking into screening abuses as well. In August 2005, U.S. Rep. Joe Barton (R-TX), Chairman of the House Energy and Commerce Committee, and Oversight and Investigations Subcommittee Chairman Ed Whitfield (R-KY) sent a letter to the plaintiffs' medical experts involved in the silica MDL litigation seeking records and information regarding public health concerns arising from various medical practices conducted in support of that litigation.[32] Finally, the Claims Resolution Management Corporation (which manages the Manville Personal Injury Settlement Trust), the Eagle-Picher Personal Injury Settlement Trust and the Celotex Asbestos Settlement Trust have each stated that they will no longer accept reports prepared by the doctors that were the subject of Judge Jack's opinion.[33]

---

30 *Id.* at 852, 843. As one physician has explained, "the chest x-rays are not read blindly, but always with the knowledge of some asbestos exposure and that the lawyer wants to file litigation on the worker's behalf." David E. Bernstein, *Keeping Junk Science Out of Asbestos Litigation*, 31 PEPP. L. REV. 11, 13 (2003) (quoting Lawrence Martin, M.D.).

31 *See* Jonathan D. Glater, *Lawyers Challenged on Asbestos*, N.Y. TIMES, July 20, 2005, at C1, *available at* 2005 WLNR 11332864.

32 *See* Press Release, *Barton, Whitfield Query Physicians Regarding Silicosis*, Aug. 2, 2005, *at* http://energycommerce.house.gov/108/News/08022005_1619.htm.

33 *See* Memorandum from David Austern, President of the Claims Resolution Management Corporation (September 12, 2005). *See also* Letter from William B. Nurre, Executive Director Eagle-Picher Personal Injury Settlement Trust, to Claimants' Counsel (October 19, 2005); Notice of Trust Policy Regarding Acceptance of Medical Reports from John L. Mekus,

(continued...)

III. Recommendations for B Reader Program Improvements and Ethics of B Readers

As noted above, the primary goals of the NIOSH B Reader program were to (1) reduce the variability of results among x-ray readers, and (2) provide for greater consensus among medical diagnoses by adopting standards and certification requirements. Unfortunately for science and medicine, some B Readers have found staggering numbers of abnormal conditions in workers even, in many cases, where there has only been minimal exposure to pneumoconiotic dusts. Because these positive B Reads come with the "stamp of approval" of a NIOSH–certified physician they are often given credence even though independent studies have shown they cannot withstand scrutiny. Thus, while the NIOSH B Reader program was aimed at reducing variability and increasing the precision of readings, the program is being used to precisely the opposite effect.

As noted above we, believe that while a B Reader Code of Ethics should be developed for certified physicians interpreting chest x-rays for the pneumoconioses, more needs to be done if the abuses described above are to be addressed.

(...continued)

Executive Director of the Celotex Asbestos Settlement Trust (October 20, 2005) (*available at* http://www.celotextrust.com/news_details.asp?nid=22).

A. Establish an Audit Program

NIOSH, as the certifying body, has a duty and obligation to ensure that persons certified use the credential bestowed upon them correctly. NIOSH conducts audits in a separate test and certification program it operates having to do with approval of respiratory protective devices used by workers to minimize exposure to toxic agents in the work environment. To preserve the integrity of the B Reader system, NIOSH should consider a mechanism to audit B Readers as well.

At this point, it is imperative that NIOSH implement an audit program for B Readers engaged in providing interpretations as expert witnesses in litigation and/or compensation programs. A primary incentive for a physician to become certified as a B Reader today apparently is to earn additional income by rendering interpretations for litigation or to serve as an expert medical witness. While still serving a need, the traditional role of a B Reader certification -- reading of chest films for epidemiologic studies, surveillance of dust-exposed workers in the clinical practice of medicine and enforcement of health regulations in the workplace -- has become secondary to its use in litigation and practically unimportant in the context of pneumoconioses radiology.

While the exact characteristics of the program should be worked out by NIOSH and stakeholders, at a minimum NIOSH should consider some type of annual questionnaire to be sent to certified B Readers to determine first if they are engaged in interpreting chest films for purposes of litigation or workers compensation. For those not engaged in such services the questionnaire could be signed and returned. For those engaged, additional responses would be required to determine such specifics as (1) the types of activity engaged in, (2) the identity of the law firms who have retained their services, (3) the percentage of professional time spent in such activities, fee structure and percentage of professional income, (4) affirmation that fees are not contingent on the outcome of the proceeding,

(5) assurance that proper notification of the medical results are being made to those being screened, (6) assurance that any diagnosis is being made on the basis of accepted medical practices (and not solely to satisfy requirements in a legal setting), and (7) affirmation that diagnoses of pneumoconioses are not being rendered based on ILO classification alone. The B Reader would have to sign the questionnaire and attest to the truthfulness of the responses. If not returned, or a B Reader falsifies a report, the certification would be revoked. B Readers would also be required to notify NIOSH at the time they begin receiving compensation for participating in litigation or compensation-related work.

In addition, the chest x-rays used as a basis for establishing the diagnoses of silicosis before Judge Jack reportedly are still in the custody of the United States District Court. NIOSH, in collaboration with the American College of Radiology Committee on Pneumoconioses, should request access to the x-rays in order to conduct a study by independent experts of all of the films included in the litigation (or at least a representative sample thereof) to determine the extent of abnormalities on the films consistent with silicosis or other pneumoconioses. The results of such a study would be useful in determining if those B Readers should be decertified.

Further, NIOSH certified B Readers should also be required to submit to NIOSH the results of chest x-ray interpretations provided for legal and compensation purposes to include data regarding whether parenchymal or pleural changes consistent with the pneumoconioses are present or absent and, if abnormalities are present, to provide details regarding profusion and shape of small opacities, size of large opacities, pleural plaques (site, calcification, extent and width of plaques in profile), and pleural thickening (site, calcification, extent and width of thickening in profile). These reports would be submitted without regard to who had retained the B Reader and without identifying the name or other personal

information concerning the claimant. This information may also be useful to NIOSH in crafting additional B Reader guidelines and requirements.

From these reports, NIOSH could create a database of information and, based on a statistical sampling weighted towards B Readers that are interpreting the largest number of films for legal and compensation purposes, seek to obtain the x-rays and have them interpreted by an independent panel of expert B Readers appointed by NIOSH. (Additionally, any pattern of suspicious readings identified by NIOSH could be subjected to having the original x-rays interpreted by the expert panel.) B Readers falling outside acceptable variance limits determined by that panel would have their certification revoked.

Finally, NIOSH should establish a process in which audits of particular B Readers could be requested by third parties.

Should NIOSH not be willing or able to incorporate an audit system into the B Reader Program, then perhaps the program should be discontinued.[34] Researchers and clinicians engaged in dust research and medical surveillance in other countries do not have a similar competency certification program, yet it does not seem to thwart those researchers or those foreign medical communities from advancing the medical understanding and recognition of dust diseases outside the United States. The B Reader certification was developed as a means to control the variability in interpretations of chest x-rays. After thirty years of experience and effort in improving the competence of physicians to interpret films for the pneumoconioses, to the extent we are seeing even great variability among B Readers, particularly in the litigation context, perhaps the program is no longer satisfying its true purpose. NIOSH must ask itself if the only purpose for maintaining this resource intensive program is to provide dueling experts for the

---

[34] *See* Glenn, *supra*, at 6.

courts. If so, the Institute could better use its funds for public health purposes and let the courts devise their own means of establishing the expertise of a physician rendering interpretations as to whether a disease is dust connected.

B. Establish a Panel of Experts in Pneumoconiosis Radiology to Serve as Court Appointed Experts

As courts increasingly deal with complex scientific questions, concerns have been expressed regarding the objectivity and reliability of both plaintiff and defense experts.[35] A survey by the Federal Judicial Center (FJC) asked judges about problems associated with scientific experts. The most frequently cited problem was that, "Experts abandon objectivity and become advocates for the side that hired them."[36]

Under Rule 706 of the Federal Rules of Evidence, judges have the authority to use court-appointed experts, even without the consent of the parties.[37] A survey by the FJC found that 87 percent of the judges believed that in some cases it would be useful to appoint their own independent experts but only 20 percent had ever appointed an expert. One reason given for not using court-appointed experts was the lack of a procedure for locating scientists that are both independent and knowledgeable.[38]

NIOSH should consider appointing a truly independent Panel of Experts in Pneumoconiosis Radiology to act as court-appointed experts to interpret and advise on chest films, and the results of other roentgenographic procedures admitted in to court proceedings. Through its long term relationship with the Committee on Pneumoconioses of the American College of Radiology, NIOSH should impanel a

---

35 *See Court Appointed Scientific Experts,* A Handbook for Experts, American Association for the Advancement of Science, Washington, (2002) at 6, available at http://case.aaas.org/handbook.pdf (last visited Dec. 28, 2005)

36 *Id.*

37 *Id.*

38 *Id.*

preeminent group of radiologists and chest physicians certified as NIOSH B Readers to assist the courts. Factors to consider in appointments would be demonstrated independence by presently not engaging as an expert in litigation, academic standing and appointments, publications in the field of pneumoconioses radiology, experience in interpreting large numbers of chest x-rays for the pneumoconioses through medical surveillance and other programs, and recognized professional standing in the appropriate medical societies.[39]

C. Specific Considerations for the B Reader Code of Ethics

The two comments of this subsection address specific subject matter in the the NIOSH proposed "Ethical Considerations for B Readers."[40]

1. Communication of Abnormal Conditions

An ethical consequence of B Readers interpreting chest x-rays in the medical-legal setting that NIOSH should consider is just how subjects are notified about abnormal findings.[41] When working with third-parties to interpret chest x-rays as an expert witness, B Readers need to determine if -- according to the law in the state they practice -- such arrangements constitute a physician-patient relationship and whether any duty to communicate findings to the individual are established. In cases where a physician-patient relationship is not established, B Readers should still apprise themselves of the procedures by which the third party will inform individuals and ensure themselves that communication takes place in an ethical

---

39 *See also* Griffin Bell, *Asbestos Litigation and Judicial Leadership The Courts Duty to Help Solve the Asbestos Litigation Crisis*, National Legal Center for the Public Interest Perspectives on Legislation, Regulation and Litigation, Vol. 6, No. 6 at 36-37 (2002). For a more detailed discussion of the potential use of independent medical panels, *see* Pendell, *supra* note 17, at 39.

40 NIOSH Safety and Health Topic: Chest Radiography, "Ethical Considerations for B Readers", <http://www.cdc.gov/niosh/topics/chestradiography/breader-ethics.html> (last visited December 21, 2005).

41 *See* Leonard Berlin, *Are Radiologists Contracted by Third Parties to Interpret Radiographs Liable for Not Communicating Results Directly to Patients*, 178 AM. J. OF RADIOLOGY 27 (2002).

manner that is sensitive to the individual. This issue and its impact on plaintiffs' in litigation was troubling to Judge Jack:

> Then there is the toll taken on the misdiagnosed Plaintiffs. If these Plaintiffs truly have abnormal x-rays, then the radiographic findings may be caused by a number of conditions other than silicosis. And when the diagnosing doctors fail to exclude these other conditions, it leaves the Plaintiffs at risk of having treatable conditions go undiagnosed and untreated.
>
> In the case of the Plaintiffs who are healthy, at least some of them can be expected to have taken their diagnoses seriously. They can be expected to have reported the diagnoses when applying for health insurance and life insurance – potentially resulting in higher premiums or even the denial of coverage altogether. They can be expected to report the diagnoses to their employers and to the Social Security Administration. And they can be expected to report the diagnoses of this incurable disease to their families and friends.
>
> These people have been told that they have a life-threatening condition: but they are not told by a doctor; they are told by a lawyer—apparently in most cases through the mail. In most cases, they never saw the doctor who diagnosed them. And in most cases, they never had the opportunity to ask the diagnosing doctor questions about the diagnosis and what it means. When dealing with this MDL and its 10,000 Plaintiffs, it is easy to forget that "statistics are human beings with the tears wiped off." (Feb. 18, 2005 Trans. at 252 (quoting Dr. Irving Selikoff).) But it should not be forgotten that a misdiagnosis potentially imposes an emotional cost on the Plaintiff and the Plaintiff's family that no court can calculate.[42]

---

[42] *See In re Silica Prods. Liab. Litig.*, 2005 WL 1593936 at * 60-61.

NIOSH should require assurance that B Readers that are interpreting chest x-rays for compensation programs or for litigation purposes, are providing the results of their interpretations to the claimants in a medically accepted manner so that those claimants have the opportunity for appropriate medical counseling and follow-up. To the extent that B Readers are providing their interpretations to another medical professional for diagnostic purposes, the B Reader should be requested to take steps to ensure that the other medical professional have undertaken similar safeguards.

2. "Clinical" versus "Legal" Diagnoses

NIOSH needs to be aware that some B Readers distinguish between a "clinical" diagnosis and a "legal diagnosis." One B Reader active in the litigation process, Dr. Ray Harron testified as follows about his "diagnosing" process:

> [I]f there's a history of exposure with some latency and then I've got an x-ray, then I can tie it together and say 'within a reasonable degree of medical certainty' this individual has whatever pneumoconiosis I think it is. And 'within a reasonable degree of medical certainty,' it is my understanding that all the lawyers on both sides of this room agree means better than a 50 percent chance that this is what the diagnosis is. It's not a diagnosis the way a treating physician would have to make a diagnosis....[43]

Dr. Harron explained that based upon diagnoses "to a reasonable degree of medical certainty," he would not "put [the clients] on drugs, do radiation therapy, put radium in them, [or] refer them to a surgeon for some kind of invasive work."[44] Stated differently, Dr. Harron appeared to treat "reasonable degree of medical certainty" as "a legal standard and not a real diagnosis."[45]

The current draft of the B Reader Code of Ethics contains a code that reads: "B Readers shall recognize the limitations of chest radiograph classifications, and

---

43 *See In re Silica Prods. Liab. Litig., Daubert Hearings*, Feb. 16, 2005, Tr. at 267-268 (testimony of Dr. Harron).

44 *See id.* at 305-08.

45 *See id.* at 268; *see also id.* at 305-08.

shall not make clinical diagnoses based on chest radiograph classifications alone.[46]" The code should make clear (1) that whether or not a physician-patient relationship has been established is not dependant upon the setting ("clinical" vs. "legal"), and (2) that "diagnoses" of any kind, especially for litigation or compensation purposes, are not to be made on the basis of a chest x-ray alone.[47]

IV. Conclusion

It is clear that the original purpose of the B Reader program -- to serve as a unique quality assurance program -- has been completely overtaken by its use in the medical-legal setting. While it is a shared responsibility of the courts, state medical licensing boards, and professional medical societies to maintain integrity in expert medical testimony, it is imperative that NIOSH, as the agency that certifies the competence of B Readers, take steps to protect the respectability of its certification. While the ethical guidelines are an important first step, NIOSH can and should do much more to make sure that original goals of the B Reader program are achieved.

---

[46] NIOSH "Ethical Considerations of B Readers," *supra*, ¶ 3.

[47] *See* Ross, *supra*, at 1120-28.

SUBMISSION OF THE COALITION FOR LITIGATION JUSTICE, INC., AMERICAN INSURANCE ASSOCIATION, NATIONAL ASSOCIATION OF MANUFACTURERS, NATIONAL FEDERATION OF INDEPENDENT BUSINESS LEGAL FOUNDATION, NATIONAL ASSOCIATION OF WHOLESALER-DISTRIBUTORS, PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA, NATIONAL ASSOCIATION OF MUTUAL INSURANCE COMPANIES, AMERICAN TORT REFORM ASSOCIATION, AND INTERNATIONAL SAFETY EQUIPMENT ASSOCIATION IN RESPONSE TO THE REQUEST FOR COMMENTS ON NIOSH'S DRAFT "RECOMMENDATIONS FOR APPLYING THE INTERNATIONAL LABOUR OFFICE (ILO) INTERNATIONAL CLASSIFICATION OF RADIOGRAPHS OF PNEUMOCONIOSES IN MEDICAL DIAGNOSIS, RESEARCH AND POPULATION SURVEILLANCE, WORKER HEALTH MONITORING, GOVERNMENT PROGRAM ELIGIBILITY, AND COMPENSATION SETTINGS"

I. Page 1, sentence beginning at line 14:

As NIOSH notes in its November 17, 2005 Federal Register announcement inviting comments on the use of the ILO classification system by NIOSH B Readers, the proceedings in the federal silica MDL in the U.S. District Court for the Southern District of Texas raised serious questions regarding the ethical conduct of NIOSH certified B Readers in diagnosing cases of silicosis. The conduct of certain NIOSH certified B Readers has also been a problem for many years in connection with litigation involving alleged exposures to asbestos. It is undisputed that the B Reader certification has become of primary importance in litigation involving asbestos and silica and, unfortunately, is of secondary importance for research purposes, worker health surveillance, and medical diagnosis in the regulatory setting. Yet the draft recommendations do not address the application of the ILO system in litigation by B Readers. NIOSH should redraft the recommendations with guidance for application in the legal setting and re-post for additional comments from affected parties.

II. Page 1, sentence beginning at line 33:

NIOSH should cite to references regarding the controversial use of the ILO system in the non-research setting.

III. Page 1, issue 5) at line 43:

We support the use of quality control films for "calibrating" readers in order to classify films in a more consistent and precise manner mentioned here and elsewhere in the document. We are not aware of a set, or sets, of films that demonstrate the patterns consistent with the pneumoconioses that could be used for this purpose. It would seem that only researchers in academia involved in reading large numbers of films for the pneumoconioses with access to large film archives would be able to develop such a practical tool. If such "calibration sets" are not available, this would seem a worthwhile project for NIOSH to pursue (perhaps in collaboration with the Committee on Pneumoconioses of the American College of Radiology), that once developed could be produced in quantity and purchased from the institute and serve to improve the variability of readers. We urge NIOSH to allocate necessary funds from its research budget to the development of standard sets of "calibration" films for utilization in quality assurance of readings by B Readers and others interpreting chest x-rays according to the ILO System.

IV. Page 2, paragraph at line 16:

We are confused as to the purpose and inclusion of this paragraph. We recognize that this guidance will be posted on the NIOSH web site where the general public will have access, but it seems the intent and purpose of the guidance is for applying the ILO Classification System by medical professionals, researchers, compensation benefits administrators and others using the ILO Classification System in each of the five topic areas addressed in the recommendations. The paragraph is written for dust-exposed workers experiencing symptoms on how to find appropriate medical care. Of course this is well intentioned but we fail to see how seeking medical care for symptoms relates to the application of the ILO Classification System.

V. Page 5 at line 2:

We do not understand why "Population Surveillance" is included in this section. The guidance in the section seems intended for application of the ILO System in research. This section does not appear to offer any guidance for application of the ILO System in population surveillance. It would seem that population surveillance is more associated with medical surveillance of workers or worker health monitoring. Indeed, the next major section on worker health monitoring has a subsection entitled, "Use of health monitoring data for population surveillance purposes." Perhaps the title of this section should be revised.

VI. Page 6, paragraph at line 9:

As discussed above, we strongly support and encourage NIOSH to develop set(s) of "calibration" films to be used for quality assurance purposes to control reader "drift" and dishonest interpretations from being provided in the use of the ILO System by B Readers.

VII. Page 13, lines 7-14:

We agree that the ILO System should not be used to determine impairment and establish compensation payments. However, as a useful reference for those needing information on evaluating impairment of the respiratory system, we recommend NIOSH reference Chapter 5, of the AMA Guides for the Evaluation of Permanent Impairment.

VIII. Page 14, paragraph at line 26:

Again, we strongly encourage NIOSH to develop set(s) of "calibration" films to be used for quality assurance purposes to control reader "drift" and dishonest interpretations from being provided in the use of the ILO System by B Readers.